

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[HYDROXYCHLOROQUINE,HYDROXYCHLOROQUINE DIPHOSPHATE,HYDROXYCHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	15-Mar-2020	To:	03-Jun-2020
MedDRA® Version* :	23.0			
Total Cases**:	4796			
Number of Pages:	3430			

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

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

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

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

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

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

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

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2020	15620376	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556697-00		39 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown	Intravenous (Not Otherwise Specified)		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Xeljanz			C	Oral			Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Joint Swelling; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Product Use Issue;	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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Rheumatoid Arthritis;	Sulfasalazine	S	Unknown	Not Reported
Therapeutic Product Effect	Plaquenil	S	Unknown	Not Reported
Decreased; Weight	Gold	S	Unknown	Not Reported
Bearing Difficulty	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	11350033	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-PFIZER INC- 2015262877		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Enbrel			S	Subcutaneous	Unk		Pfizer
Arthropathy; C-Reactive	Enbrel			S				Pfizer
Protein Abnormal; C-								

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

Reactive Protein Increased;	Methotrexate Sodium	S	Unknown	Unk	Pfizer
Contraindicated Product Administered; Death;	Methotrexate Sodium	S			Pfizer
Deep Vein Thrombosis;	Methotrexate Sodium	S	Intra-arterial	Unk	Pfizer
Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Photosensitivity Reaction; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Thrombosis; Urticaria	Methotrexate Sodium	S			Pfizer
	Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
	Sulfasalazine	S			Pfizer
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S			Not Reported
	Kineret	S		Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk, Single Use Vial	Not Reported

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Ilaris	S	Unknown	Unk, Single Use Vial	Not Reported
Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ilaris	S	Unknown	Unk (Powder For Injection)	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S			Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S			Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
Apo-Sulfasalazine	S		Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S			Not Reported
Oxyquinoline Sulfate	S			Not Reported
Oxyquinoline Sulfate	S			Not Reported
Xeljanz	C	Oral	Unk Unk, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Q2wk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Prednisone	C		Unk Unk, Qd	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	11382867	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-PFIZER INC-2015267393		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort;	Enbrel	S	Subcutaneous	Unk	Pfizer
Arthralgia; Coeliac	Enbrel	S	Unknown	Unk	Pfizer
Disease; Contraindicated	Methotrexate Sodium	S	Oral	Unk	Pfizer
Product Administered;	Methotrexate Sodium	S	Oral	Unk	Pfizer
Drug Ineffective; Fatigue;	Sulfasalazine	S	Unknown	500 Milligram, Unk	Pfizer
Grip Strength Decreased;	Sulfasalazine	S	Unknown	Unk	Pfizer
Headache; Injection Site	Infliximab Hospira	S	Unknown	Unk	Not Reported
Reaction; Joint Swelling;	Xeljanz	S	Unknown	5 Milligram, Bid	Pfizer
Loss Of Personal	Xeljanz	S	Unknown	5 Mg, Unk	Pfizer
Independence In Daily	Actemra	S	Unknown	Unk	Not Reported
Activities; Musculoskeletal	Humira	S	Subcutaneous	Unk	Not Reported
Stiffness; Nail Disorder;	Cimzia	S	Subcutaneous	Unk	Not Reported
Onychomadesis;	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Onychomycosis	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

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

Hydroxychloroquine	S	Oral	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Arava	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	12091497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016085227		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Product Use Issue; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Enbrel			S	Subcutaneous	50 Mg, Weekly (50 Milligram, Qwk)		Pfizer	
	Enbrel			S	Unknown	Unk		Pfizer	
	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Xeljanz			S	Oral	5 Mg, 2x/Day (5 Milligram, Bid)		Pfizer	
	Xeljanz			S		5 Ng, 2x/Day (5 Nanogram, Bid)		Pfizer	
	Xeljanz			S		5 Mg, 2x/Day (5 Milligram, Bid)		Pfizer	
	Sulfasalazine			S		Taken For 2 Years		Pfizer	
	Sulfasalazine			S	Oral	500 Mg, 1x/Day (500 Milligram, Qd)		Pfizer	
	Sulfasalazine			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk (25 Milligram)		Pfizer	
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly (25 Milligram, Qwk)		Pfizer	
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk (25 Milligram)		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Plaquenil			S	Unknown	400 Mg, Taken For 2 Years		Not Reported	
	Plaquenil			S	Oral	200 Mg, 2x/Day (200 Milligram, Bid)		Not Reported	

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Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		40 Mg, 2x/Week (40 Milligram, Q2wk)	Not Reported
Humira	S		40 Mg, Unk (40 Milligram)	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk (400 Milligram)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Azathioprine	S		100 Mg, Unk (100 Milligram)	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	50 Mg, Unk (50 Milligram)	Not Reported
Minocycline Hydrochloride	S		Unk	Not Reported
Minocycline	S		Unk	Not Reported
Azathioprine	S	Unknown	100 Mg, Unk (100 Milligram)	Not Reported
Arava	S	Oral	20 Mg, Weekly (20 Milligram, Qwk)	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	20 Mg, 1x/Day (20 Milligram, Qd)	Not Reported
Apo-Minocycline	S		50 Mg, Unk	Not Reported
Orencia	S		Unk, Monthly (Qmo)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Mg, Unk (400 Milligram)	Not Reported

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Hydroxychloroquine Sulfate	S		400 Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Leflunomide	C	Unknown	20 Unk, Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Amoxil	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Clavulin	C		Unk	Not Reported
Amoxicillin Trihydrate And Clavulanate Potass	C	Unknown	Unk	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Unk (Powder For Solution For Intravesical Use)	Not Reported
Bcg Vaccine	C	Unknown	Unk (Powder For Solution For Intravesical Use)	Not Reported
Adalimumab	C		Unk	Not Reported
Risedronate	C	Oral	35 Mg, Qwk	Not Reported
Amoxicillin	C		Unk	Not Reported
Amoxil [Amoxicillin Trihydrate]	C		Unk	Not Reported
Hydroxychloroquine	C	Subcutaneous	400 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	400 Milligram	Not Reported
Hydroxychloroquine	C	Unknown	100 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	12185482	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2016145185		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer	
Blood Creatinine	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer	
Increased; Blood									
Magnesium Increased;	Methotrexate Sodium			S	Subcutaneous	7.5 To 12.5 Mg, Weekly		Pfizer	

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Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Joint Swelling; Mobility Decreased;	Methotrexate Sodium	S	Subcutaneous	7.5 To 12.5 Mg, Weekly	Pfizer
Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia;	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly	Pfizer
Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbycusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly	Pfizer
	Sulfasalazine	S	Oral	2.5 G, Daily	Pfizer
	Sulfasalazine	S	Oral	500 Mg, 1x/Day	Pfizer
	Gabapentin	S	Oral	100 Mg, 2x/Day	Pfizer
	Gabapentin	S	Unknown	100 Mg, 1 Every 2 Days	Pfizer
	Celebrex	S	Oral	Unk	Pfizer
	Celebrex	S		Unk, Occlusive Dressing Technique	Pfizer
	Fentanyl	S	Unknown	Unk	Pfizer
	Fentanyl	S	Unknown	Unk	Pfizer
	Celecoxib	S	Oral	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 1x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
	Xeljanz	S	Oral	5 Mg, Unk	Pfizer
	Plaquenil	S	Unknown	400 Mg, Daily (Qd)	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Every 3 Weeks	Not Reported
	Myochrysine	S	Intramuscular	60 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
	Orencia	S	Subcutaneous	Unk, Weekly	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Cyclic Q3wk	Not Reported
	Orencia	S	Vaginal	750 Mg, Monthly	Not Reported

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

Nortriptyline Hydrochloride/Perphenazine	S	Oral	10mg Tablets 1-3 Tablets Every Evening	Not Reported
Nortriptyline Hydrochloride/Perphenazine	S	Oral	10 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Monthly	Not Reported
Actemra	S	Oral	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Cyclic Q4wk	Not Reported
Hydroxychloroquine	S	Unknown	400 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Apo Fentanyl Matrix	S		Unk	Not Reported
Apo Celecoxib	S	Oral	Unk	Not Reported
Apo Gabapentin	S		Unk	Not Reported
Apo Gabapentin	S	Oral	100 Mg, 2x/Day	Not Reported
Arava	S	Oral	20 Mg, Qd	Not Reported
Fentanyl Matrix	S	Unknown	Unk Patch	Not Reported
Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Monthly	Not Reported
Omega-3 [Salmo Salar Oil]	S		Unk	Not Reported
Omega-3 Fatty Acids	C		1200 Mg, 2x/Day	Not Reported
Multivitamin	C		Unk	Not Reported
Tecta	C		40 Mg, Daily	Not Reported
Diphenoxylate	C		2.5/0.25 Milligram, Qd	Not Reported
Vitamin D	C		400 Iu, Daily	Not Reported
Vitamin D	C		400 Df, 1x/Day	Not Reported
Actonel	C		36 Mg, Weekly	Not Reported
Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported
Prednisone	C		Unk5.0 Gbq, Qd	Not Reported
Aclasta	C	Intravenous (not	750 Mg, Monthly	Not Reported

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

			otherwise specified)	
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, (Every Four Weeks)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C		Unk	Not Reported
Calcium	C		Unk	Not Reported
Fergon	C		300 Mg, Daily	Not Reported
Fergon	C		300 Mg, 1x/Day	Not Reported
Fergon	C		Unk	Not Reported
Tylenol	C	Oral	500 Mg 2 Tabs, 1x/Day	Not Reported
Tylenol	C	Oral	1000 Mg, 1x/Day	Not Reported
Nexium	C		40 Mg, 2x/Day	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day At Bedtime	Not Reported
Trazodone Hcl	C	Oral	50 Mg, 1x/Day	Not Reported
Nasonex	C	Nasal	2 Sprays, 2x/Day	Not Reported
Nasonex	C		Unk Unk, Bid (Spray Metered Dose)	Not Reported
Nasonex	C		2 Df, 2x/Day	Not Reported
Percocet	C		1 Tab 4-6h As Needed	Not Reported
Lomotil	C		2.5mg 3-4 Times/Day	Not Reported
Lomotil	C		2.5 Mg, Qd	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, 2x/Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk, 1x/Day	Not Reported
Diphenoxylate Hydrochloride	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, 2x/Day	Not Reported

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

Esomeprazole Magnesium Trihydrate	C	Unknown	40 lu, 1x/Day	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C		1 Df, Unk	Not Reported
Trazodone	C		Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, 2x/Day	Not Reported
Esomeprazole	C		400 Mg, 2x/Day	Not Reported
Esomeprazole	C		Unk	Not Reported
Loperamide Hydrochloride	C		2.5 Mg, Unk	Not Reported
Ergocalciferol	C		400 lu, 1x/Day	Not Reported
Ergocalciferol	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1x/Day	Not Reported
Tecta	C		40 Milligram, Qd	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclic Qh	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega 3 2100	C		1200 Mg, 2x/Day	Not Reported
Omega 3 2100	C		Unk, Q2wk	Not Reported
Genteal [Hypromellose]	C		Unk	Not Reported
Fish Oil	C		1200 Mg, 2x/Day	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Ascorbic Acid	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Biotin	C		Unk	Not Reported
Nicotinamide	C		Unk	Not Reported
Pantoprazole	C		400 Mg, 1x/Day	Not Reported
Pantoprazole	C		40 Mg, 1x/Day	Not Reported
Pantoprazole	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

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

Pyridoxine Hydrochloride	C		Unk	Not Reported
Sodium	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Thiamine Hydrochloride	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vit D3	C		Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Ferrous Fumarate	C		Unk	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C		1200 Mg, 2x/Day	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Docosahexaenoic Acid/Eicosapentaenoic Acid	C	Unknown	Unk, Q2wk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Retinol Palmitate	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Sodium Ascorbate	C		Unk	Not Reported
Thiamine Mononitrate	C		Unk	Not Reported
Vitamine C	C		Unk	Not Reported
Vitamin D3	C		Unk	Not Reported
Loperamide	C		Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	C		Unk	Not Reported
Nortriptyline	C		Unk	Not Reported
Oxycodone And Acetaminophen	C		Unk	Not Reported
Epa Dha 720	C		Unk	Not Reported

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

Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Unk	Not Reported
Thiamine	C		Unk	Not Reported
Vitamin E [Tocopherol]	C		Unk	Not Reported
Cholecalciferol	C		Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Vitamin B3	C		Unk	Not Reported
Vitamin B1 [Thiamine]	C		Unk	Not Reported
Vitamin B6	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Acetaminophen	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	12301979	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2014315082		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom;	Celebrex			S		200 Mg, 2x/Day (Bid)		Pfizer	
	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Enbrel			S				Pfizer	
	Methotrexate Sodium			S		Unk, Daily (Qd)		Pfizer	
	Methotrexate Sodium			S				Pfizer	
	Arava			S		Unk		Not Reported	
	Arava			S				Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	Unk, Monthly		Not Reported	
	Actemra			S				Not Reported	
	Plaquenil			S		Unk		Not Reported	
	Apo-Prednisone			S		14 Mg, 1x/Day		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk, 2x/Day		Not Reported	
	Prednisone			S	Unknown	14 Mg, 1x/Day		Not Reported	

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

Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Dilaudid	C		4 Mg, 3x/Day	Not Reported
	Dilaudid	C			Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Furosemide	C		Unk, 1x/Day	Not Reported
	Hydromorph Contin	C		18 Mg, 3x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	12302274	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2016221150		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood	Enbrel			S	Unknown	25 Mg, Weekly		Pfizer
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Pfizer
	Enbrel			S	Unknown	25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Pfizer
	Enbrel			S	Unknown	50 Mg, Unk		Pfizer
	Etanercept			S	Unknown	25 Mg, 2x/Week		Pfizer
	Etanercept			S	Unknown	50 Mg, Weekly		Pfizer
	Celebrex			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	15.5 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Q4wk		Pfizer
	Methotrexate Sodium			S	Unknown	12 Mg, Q4wk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer

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

Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Unknown	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	Unk	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Pfizer

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

Sulfasalazine	S	Unknown	500 Mg, Unk	Pfizer
Sulfasalazine	S	Unknown	Unk	Pfizer
Infliximab Hospira	S	Intravenous (not otherwise specified)	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported
Rituxan	S	Unknown	1000 Mg, 2x/Day	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported

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

Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	Unk	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate	S	Unknown	70 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported

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

Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Alendronate Sodium	C	Unknown	Unk	Not Reported
Alendronate Sodium	C	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Prednisone	C	Unknown	10 Mg	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, 1x/Day	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, 2x/Day	Not Reported
Prednisolone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	12338904	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016241427		53 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Contraindicated Product	Enbrel	S	Subcutaneous	50 Mg, Once A Week	Pfizer
Administered; Drug	Methotrexate Sodium	S	Oral	25 Mg, Monthly	Pfizer
Ineffective; Dyspnoea;	Methotrexate Sodium	S	Oral	25 Mg, Unk	Pfizer
Impaired Work Ability;	Tofacitinib Citrate	S	Oral	5 Mg, 2x/Day	Pfizer
Joint Lock; Joint Swelling;	Xeljanz	S	Oral	5 Mg, Bid (2 Every 1 Day)	Pfizer
Limb Discomfort; Loss Of	Xeljanz	S	Oral	5 Mg, 2x/Day	Pfizer
Personal Independence In	Xeljanz	S	Unknown	5 Mg, Bid	Pfizer
Daily Activities; Mass;	Actemra	S	Intravenous (not	8 Mg/Kg, Qd (1 Every 24	Not Reported
Mobility Decreased;	Actemra	S	otherwise specified)	Hours)	
Musculoskeletal Stiffness;	Humira	S	Intravenous (not	8 Mg/Kg, Monthly	Not Reported
Pain; Peripheral Swelling;	Humira	S	otherwise specified)		
Rash; Skin Mass; Therapy	Humira	S	Subcutaneous	40 Mg, Once Every Two	Not Reported
Non-Responder	Humira	S	Subcutaneous	40 Mg	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported
	Remicade	S	otherwise specified)		
	Remicade	S	Subcutaneous	50 Mg, Weekly (1 Every 1	Not Reported
	Apo-Hydroxyquine	S	Oral	Week(S))	
	Hydroxychloroquine	S	Oral	400 Mg, Qd (1 Every 24	Not Reported
	Cimzia	S	Oral	Hours)	
	Orencia	S	Subcutaneous	400 Mg, Qd	Not Reported
	Prednisone	S	Subcutaneous	Unk	Not Reported
	Arava	S	Unknown	125 Mg, Weekly	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Prednisone Acetate	S	Oral	20 Mg, Qd (1 Every 24	Not Reported
	Ergocalciferol	C	Hour)		
	Sulfasalazine	C	Oral	400 Milligram, Qd	Not Reported
		C	Unknown	Unk	Not Reported
		C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthralgia; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Infliximab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Dose		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
Leflunomide			S		Unk		Not Reported	
Desoximetasone			S		Unk		Not Reported	
Humira			S		Unk		Not Reported	
Methadone			S		Unk		Not Reported	
Rampril			S		Unk		Not Reported	

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

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
Estrogel	C	Unknown	1.0 Df Qd	Not Reported
Estradiol	C		Unk, Tid	Not Reported
Calcium	C		500 Milligram, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
Cosopt	C		Unk, 2x/Day	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Vitamin D	C		10000 Unit, Weekly	Not Reported
Jampk20	C		1500 Mg, 1x/Day	Not Reported
Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
Baclofen	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	12659993	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2016335872		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral;	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	1 G, Qd		Pfizer
	Actemra			S	Unknown	Unk		Not Reported

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

Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	200 Mg, 2x/Day	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Mg, 1x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown	11.2 Milligram, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day(Bid)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	1 Gram, Qd	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prednisone	C	Unknown	15 Mg, Daily (Qd)	Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13033547	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-095488			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection;	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb	
	Enbrel			S	Unknown	Unk		Not Reported	

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

Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Gold	S	Unknown	50 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	8 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13128781	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017005116		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen	
	Enbrel			S	Unknown	25 Mg, Unk		Amgen	
	Enbrel			S	Subcutaneous	Unk		Amgen	
	Enbrel			S	Unknown	25 Mg, Bid		Amgen	
	Arava			S	Unknown			Not Reported	
	Rituximab			S	Unknown	1 Gram		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	20 Mg, Qwk		Not Reported	
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Not Reported	
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Not Reported	

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

Anakinra	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Cyclical	Not Reported
Humira	S	Unknown	40 Mg, Q2wk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6wk	Not Reported
Remicade	S	Unknown	300 Mg, Unk	Not Reported
Remicade	S	Unknown	300 Mg, Cyclical	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Hydroxyquine	S	Unknown	20 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
Methotrexate	S	Unknown	20 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	15 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Methotrexate	S	Unknown	200 Mg, Qwk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	1 G, Bid	Not Reported

FDA Adverse Event Reporting System

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Wellbutrin			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13549390	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017071781		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Supeudol			C	Unknown	5 Mg, As Necessary		Not Reported	
	Methotrexate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13761472	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017105360		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Amgen	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported	
	Celebrex			C		Unk, As Necessary		Not Reported	
	Xeljanz			C		Unk		Not Reported	

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

Prednisone			C		Unk Unk, As Necessary			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13805299	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017112357		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Glaucoma Surgery; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Amgen	
	Enbrel			S	Unknown	Unk		Amgen	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Methotrexate Sodium			S	Oral	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	
	Lyrica			C	Oral	Unk		Not Reported	
	Lyrica			C	Unknown	Unk		Not Reported	
	Prednisone			C	Oral	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Arava			C		Unk		Not Reported	
	Codeine			C	Unknown	Unk		Not Reported	

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Tylenol [Paracetamol]			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13862390	NON-EXPEDITED		HO, OT	CA-AMGEN- CANSP2017119633		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip Arthroplasty; Infection; Knee Arthroplasty; No Adverse Event; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Fusion Surgery; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Enbrel			S	Unknown	Unk		Amgen	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Cosentyx			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Rituxan			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported	
	Naprosyn			C	Unknown	Unk		Not Reported	
	Erythromycin			C		Unk		Not Reported	
	Morphine			C	Topical	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13908900	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017128230		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

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

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

Abatacept	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13909412	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017128000		59 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	2.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Milligram, Qwk		Not Reported

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

Methotrexate	S	Unknown	Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Folic Acid	C		2.5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish	C	Unknown	Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13909421	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017127635		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Enbrel			S	Unknown	Unk		Amgen	
Arthralgia; Diarrhoea;	Enbrel			S	Unknown	Unk		Amgen	
Disease Recurrence; Drug Ineffective; Joint Swelling;	Enbrel			S	Unknown	Unk		Amgen	
Lower Respiratory Tract Infection; Pulmonary	Actemra			S	Unknown	Unk		Not Reported	
Mass; Rheumatoid	Arava			S	Unknown	Unk		Not Reported	
Arthritis; Rheumatoid	Cimzia			S	Subcutaneous	Unk (Single Use Prefilled		Not Reported	

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

Factor Positive					Syringe)	
	Cimzia	S	Unknown	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Plaquenil	S	Unknown	Unk		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Leflunomide	S	Unknown	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Apo-Leflunomide	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Simponi	S	Unknown	Unk		Not Reported
	Rituximab	S	Intravenous drip	Unk		Not Reported
	Imuran	C	Unknown	Unk		Not Reported
	Arthrotec	C	Unknown	Unk		Not Reported
	Ergocalciferol	C	Unknown	Unk		Not Reported
	Ergocalciferol	C		Unk		Not Reported
	Azathioprine	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	13926256	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017375036		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper;	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer	

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Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate Sodium	S	Oral	17.5 Mg, Qwk	Pfizer
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q2wk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Bid	Not Reported
	Sulfasalazine	C		Unk	Not Reported

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

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

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	14185061	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017170005		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Enbrel			S	Subcutaneous	50 Milligram		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	200 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Restasis			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Unknown	25 Milligram, Q2wk		Amgen
	Enbrel			S	Unknown	25 Milligram, Qwk		Amgen
	Enbrel			S	Unknown	25 Milligram		Amgen
	Enbrel			S	Unknown	25 Milligram, Cyclical		Amgen

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	14190825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017490362		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective;	Enbrel	S	Subcutaneous	50 Mg, Unk	Pfizer
Emotional Disorder;	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Pfizer
Herpes Zoster;	Sulfasalazine	S	Oral	1000 Milligram, Bid	Pfizer
Hypothyroidism;	Actemra	S	Unknown	Unk	Not Reported
Inappropriate Schedule Of	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Product Administration;	Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Injury; Malignant	Hydroxychloroquine	S	Unknown	Unk	Not Reported
Melanoma; Product Dose	Rituxan	S	Intravenous (not	Unk	Not Reported
Omission; Rheumatoid			otherwise specified)		
Arthritis	Apo-Hydroxyquine	S	Oral	200 Mg, Bid	Not Reported
	Folic Acid	C		Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Restasis	C	Unknown	Unk (Emulsion)	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	14216870	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017174939			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
Ineffective; Drug	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
Intolerance; Grip Strength	Arava			S	Unknown	20 Milligram, Qd		Not Reported
Decreased; Joint Swelling;	Humira			S	Subcutaneous	Unk		Not Reported
Pain In Extremity;	Meloxicam			S	Oral	7.5 Milligram		Not Reported
Peripheral Swelling;	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
Therapeutic Product Effect	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Not Reported
Decreased; Treatment	Plaquenil			S	Unknown	Unk		Not Reported
Failure	Mobicox			S	Oral	7.5 Milligram, Qd		Not Reported

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Hydroxychloroquine Sulfate	S	Oral		Not Reported
Sulfasalazine	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	14217819	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017175088		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Enbrel			S	Unknown	50 Milligram, Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Sulfasalazine			S	Unknown	10000 Milligram, Bid		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported	
Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	14224287	NON-EXPEDITED		OT	CA-AMGEN- CANSP2017175535		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Drug	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Unknown	Unk		Not Reported

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Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

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

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

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Amgen
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Qd		Not Reported

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Prednisone			C		10 Milligram			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	14775658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018157923			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Enbrel			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Unknown	25 Milligram		Pfizer	
	Actemra			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Sarilumab			S	Unknown	Unk		Not Reported	
	Kevzara			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15209356	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018101357			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen	
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported	
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported	
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported	
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Mg, 2 Times/Wk		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Unk, Unk (Three In One Week)		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Unk		Not Reported	

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

	Methotrexate	S	Subcutaneous	20 Mg, Qwk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15286198	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016077975		55 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

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

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Injection		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Oral	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

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

Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz	C	Unknown	2 Df, Qd	Not Reported

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

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15583667	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017372752		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Pfizer	
	Enbrel			S	Unknown	Unk		Pfizer	
	Sulfasalazine			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Oral	2.5 Milligram, Qwk		Pfizer	
	Methotrexate Sodium			S	Oral	1 Df, Weekly		Pfizer	
	Methotrexate Sodium			S	Oral	10 Milligram, Qwk		Pfizer	
	Methotrexate Sodium			S	Oral	15 Milligram, Qwk		Pfizer	
	Actemra			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Humira			S	Subcutaneous	40 Dosage Form, Q2wk		Not Reported	
	Orencia			S	Unknown	40 Milligram, Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Adalimumab			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	
	Folic Acid			C	Oral	2.5 Milligram, Qd		Not Reported	

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

Folic Acid	C		Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Pantoprazol	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil [Tenofovir Disoproxil Fumarate]	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	7.5 Mg, Daily	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported
Tenofovir	C		Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram, Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Pantoprazole Sodium	C	Unknown	Unk	Not Reported
Pantoprazole Bluefish [Pantoprazole Sodium Sesquihydrate]	C	Unknown	Unk	Not Reported
Pantoprazole	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15585218	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2540122-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Disability; Drug Ineffective; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S				Not Reported	
	Etanercept			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S				Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Gp2013		Not Reported	
	Rituximab			S	Unknown			Not Reported	

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

Site Reaction; Joint Destruction; Joint Effusion; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Leflunomide Leflunomide Sulfasalazine Plaquenil Tocilizumab Infliximab Infliximab Orencia Orencia Abatacept Actemra Actemra Enbrel Enbrel	S S S S S S S S S S S S S	Oral Unknown Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Subcutaneous	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Disorder;	Humira			S	Subcutaneous			Not Reported
Bronchiectasis; Bursitis;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection;	Sulfasalazine			S	Unknown			Not Reported
Inflammation; Joint Range Of Motion Decreased; Leg Amputation; Localised	Arava			S	Unknown			Not Reported
Infection; Osteoporosis;	Methotrexate			S	Unknown			Not Reported
Peripheral Vascular Disorder; Photosensitivity	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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

Reaction; Pneumonia;	Azathioprine	S	Unknown	Not Reported
Renal Failure; Respiratory	Plaquenil	S	Unknown	Not Reported
Tract Infection;	Infliximab	S	Unknown	Not Reported
Rheumatoid Arthritis; Skin	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Discolouration; Skin Ulcer;	Acidophilus	C		Not Reported
Staphylococcal Infection;	Aspirin	C		Not Reported
Swelling; Synovitis;	Calcium	C		Not Reported
Tenosynovitis;	Deflazacort	C		Not Reported
Therapeutic Product Effect	Dilaudid	C		Not Reported
Incomplete	Ergocalciferol	C		Not Reported
	Hydromorphone Hydrochloride	C	Intramuscular	Not Reported
	Januvia	C		Not Reported
	Kenalog	C	Intra-articular	Not Reported
	Lidocaine	C	Topical	Not Reported
	Metronidazole	C		Not Reported
	Nitroglycerin	C		Not Reported
	Pantoloc	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Pregabalin	C		Not Reported
	Risedronate	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Salbutamol	C		Not Reported
	Triamcinolone	C		Not Reported
	Tylenol	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Triamcinolone Acetonide	C		Not Reported
	Salicylic Acid	C		Not Reported
	Rosuvastatin	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15687047	NON-EXPEDITED		OT	CA-AMGEN- CANSP2018170659		23 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective; No Adverse Event	Enbrel	S	Subcutaneous	Unk	Amgen
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Orencia	S	Oral	200 Milligram, Bid	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	C		Unk	Not Reported
	Methotrexate	C	Oral	20 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15700850	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018119653		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Condition Aggravated; Condition Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Enbrel			S		Unk		Pfizer	
	Sulfasalazine			S		Unk		Pfizer	
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer	
	Adalimumab			S	Unknown	Unk		Not Reported	
	Act Esomeprazole			S	Unknown	Unk		Not Reported	
	Ciclosporin			S	Unknown	Unk		Not Reported	
	Esomeprazole Sodium			S	Unknown	Unk		Not Reported	
	Folic Acid			S		Unk		Not Reported	

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

Nicotinamide	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Thiamine Hydrochloride	S		Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	162 Mg, Qwk, Six Months	Not Reported
Kevzara	S		20 Mg, Unk (Every 14 Days For Eight Weeks)	Not Reported
Kevzara	S	Subcutaneous	20 Milligram, 1 Every 2 Weeks	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, 1x/Day	Not Reported
Sarilumab	S	Subcutaneous	20 Mg, 2x/Week	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Riboflavin	C		Unk	Not Reported
Vitamin A [Retinol]	C		Unk	Not Reported
Vitamin C [Ascorbic Acid]	C		Unk	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
Dexpanthenol	C		Unk	Not Reported
Esomeprazole Magnesium Trihydrate	C		Unk	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
Esomeprazole	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15704441	NON-EXPEDITED		OT	CA-AMGEN-CANSP2018174077			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported

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

Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen	C		650 Milligram, Bid	Not Reported
Aluminium Acetate W/Benzethonium Chloride	C		Unk	Not Reported
Atacand	C		Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hydrodiuril	C	Unknown	Unk	Not Reported
Neurontin	C	Unknown	600 Milligram, Tid	Not Reported
Premarin	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	650 Mg, Bid	Not Reported
Aluminium Acetate	C	Unknown	Unk	Not Reported
Benzethonium Chloride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	15924554	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2653465-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported	
Alopecia; Glossodynia;	Actemra			S	Intravenous (not			Not Reported	
Pain; Pemphigus;					otherwise specified)				
Swelling; Systemic Lupus	Arava			S	Oral			Not Reported	
Erythematosis	Cimzia			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Oral			Not Reported	

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

Etanercept	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine[Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16120373	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019045643		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Drug Ineffective; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported	
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported	
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported	

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

Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk (Tablets)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Orencia	S	Unknown	75 Milligram, Qmo	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Plaquenil S	C		Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Risedronate	C	Oral	35 Milligram, Qwk	Not Reported
Cimzia	C	Subcutaneous	200 Milligram	Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S				Sanofi
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg		Not Reported
	Orencia			S				Not Reported
	Rituxan			S		Solution Intra Venous		Not Reported
	Salazopyrin			S				Not Reported
	Actemra			C				Not Reported

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	Bifidumbacterin	C	Not Reported
	Celebrex	C	Not Reported
	Loperamide	C	Not Reported
	Methotrexate	C	Not Reported
	Pantoprazole	C	Not Reported
	Xeljanz	C	Not Reported

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

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

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Aleve			S	Unknown	Unk		Bayer
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Kineret			S	Subcutaneous	50.0 Mg, Qd		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Oral	5.0 Mg, Bid		Not Reported
	Enbrel			S	Subcutaneous	25.0 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg, 4iw		Not Reported
	Enbrel			S	Subcutaneous	25 Unk		Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	70.0 G		Not Reported

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Positive; Juvenile	Hydroxychloroquine	S	Oral	5.0 Mg, Qd	Not Reported
Idiopathic Arthritis; Loss	Infliximab	S	Unknown	5.0 Mg	Not Reported
Of Personal Independence	Infliximab	S	Intravenous (not	3.0 Mg, Ow	Not Reported
In Daily Activities; Mobility			otherwise specified)		
Decreased; Nausea;	Methotrexate	S	Subcutaneous	15.0 Mg, Ow	Not Reported
Obesity; Off Label Use;	Orencia	S	Intravenous (not	250.0 Mg, Q1mon	Not Reported
Polyarthritis; Product Use			otherwise specified)		
In Unapproved Indication;	Prednisone	S	Oral	3.0 Mg, Bid	Not Reported
Psoriasis; Red Blood Cell	Prednisone	S	Oral	5.0 Unk	Not Reported
Sedimentation Rate	Sulfasalazine	S	Oral	250.0 Mg, Qd	Not Reported
Increased; Septic Shock;	Tocilizumab	S	Intravenous (not	280.0 Mg, Q2wk	Not Reported
Synovitis; Underdose;			otherwise specified)		
Vomiting; Wheelchair User	Tocilizumab	S	Intravenous (not	280 Mg, Ow	Not Reported
			otherwise specified)		
	Triamcinolone	S	Subcutaneous	25.0 Mg, Q2wk	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Gamastan	S		70.0 G	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5.0 Mg/Kg, Qd	Not Reported
	Naproxen	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Immunoglobulin I.V	S	Intravenous (not	70.0 G	Not Reported
			otherwise specified)		
	Triamcinolone Hexacetonide	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16330442	NON-EXPEDITED		OT	CA-AMGEN- CANSP2019077665			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug	Enbrel			S	Unknown	Unk		Amgen	
Ineffective; Hepatotoxicity;	Actemra			S	Subcutaneous	Unk		Not Reported	
Joint Swelling; Loss Of									

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

Personal Independence In Daily Activities; Therapeutic Response Decreased	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	2 Gram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Xeljanz	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16470848	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2018036164		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Unknown	Unk		Pfizer	
	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Enbrel			S	Unknown	25 Milligram, Q2wk		Pfizer	
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer	
	Methotrexate Sodium			S	Unknown	15 Milligram		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported	
	Leflunomide			S	Unknown	10 Milligram, 1x/Day		Not Reported	
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	

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

Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	10 Milligram, Qd	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Milligram 1 Every 6 Weeks	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram	Not Reported
Aleve	C		Unk Unk, As Needed	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Bupropion	C		Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16471566	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017312936		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Enbrel	S	Unknown	25 Mg, 2x/Week	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Unknown	300 Mg, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	1000 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16483146	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2017349309		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Infection; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	17.5 Mg, Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported

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Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1.0 Dosage Form, Qd	Not Reported
Hydroxychloroquine	S	Oral	300 Mg, 1x/Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Cyclic	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Plaquenil S	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, 1 Every 1 Hour(S)	Not Reported
Leflunomide	S	Unknown	1.0 Dosage Form	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Mg, 1x/Day	Not Reported
Actonel	S	Unknown	35.0 Mg, Weekly	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Risedronate	S	Unknown	Unk	Not Reported
Risedronate	S		35 Mg, Weekly	Not Reported
Methotrexate	C		Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16628388	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2863507-00		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Apo-Prednisone			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Tofacitinib Citrate			S	Unknown			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16793789	NON-EXPEDITED		OT	CA-AMGEN- CANSP2018056893		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Enbrel			S	Unknown	50 Milligram, Qwk		Amgen	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen	
	Enbrel			S	Unknown	50 Milligram, Qd		Amgen	
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported	
	Methotrexate			S	Subcutaneous	20 Milligram, Unk		Not Reported	
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported	
	Methotrexate			S	Oral	20 Milligram, Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported	
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Oral	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported	
	Orencia			S	Subcutaneous	125 Milligram, Unk		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram, Unk		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Unk		Not Reported	
	Ciclosporin			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Neoral			S	Subcutaneous	Unk		Not Reported	
	Neoral			S	Unknown	Unk		Not Reported	
	Neoral			S	Oral	Unk		Not Reported	
	Neoral			S	Subcutaneous	Unk		Not Reported	

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Remicade	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16797341	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019146895		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S	Unknown	50 Milligram		Amgen	
	Actemra			S	Unknown	Unk		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Ergocalciferol			C		Unk Unk, Qwk		Not Reported	

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

Dorzolamide Hydrochloride And Timolol Maleate	C	Unknown	Unk Unk, Bid	Not Reported
Estrogel	C		0.6 Percent, Tid	Not Reported
Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
Valsartan	C		320 Milligram, Qd	Not Reported
Xalatan	C		50 Microgram, Qd	Not Reported
Zingiber Officinale	C	Oral	500 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16807532	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019147890			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Amgen
	Actemra			S	Unknown	8 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	16848358	NON-EXPEDITED		OT	CA-AMGEN- CANSP2019155529			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Amgen
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17036954	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019493883		69 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower;	Pantoloc			S	Unknown	40 Milligram		Pfizer
Asthma; Atelectasis; Blood	Omnaris			S	Unknown	50 Microgram		Not Reported
Disorder; Blood	Alvesco			S	Unknown	200 Microgram, Qd		Not Reported
Immunoglobulin E	Ivermectin			S	Unknown	Unk		Not Reported
Increased; Bronchial Wall	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported
Thickening; Bronchiolitis;	Phosphate]							
Condition Aggravated;	Prednisone			S	Oral	5 Milligram		Not Reported
Cough; Dysphonia;	Prednisone			S	Oral	50 Milligram		Not Reported
Dyspnoea; Eosinophil	Salbutamol Sulfate			S	Unknown	100 Microgram		Not Reported
Count Increased;	Umeclidinium Bromide			S	Unknown	62.5 Microgram		Not Reported
Eosinophilic	Zenhale			S	Unknown	2 Df, Bid		Not Reported
Granulomatosis With	Sulfasalazine			C	Unknown	Unk		Not Reported
Polyangiitis; Fungal	Arava			C	Unknown	Unk		Not Reported
Infection; Infection								
Parasitic; Inflammation;								
Malaise; Oropharyngeal								
Pain; Pneumonia;								
Pneumonitis; Productive								
Cough; Secretion								
Discharge; Sinusitis; Skin								
Disorder; Sleep Disorder								
Due To A General Medical								
Condition; Spirometry								
Abnormal; Suprapubic								
Pain; Systemic								
Inflammatory Response								
Syndrome; Therapeutic								
Product Effect Incomplete;								
Underweight; Vasculitis;								
Weight Decreased;								
Wheezing								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17038283	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1116759		62 YR	Female	CAN

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Abscess;	Furosemide			S	Unknown			Ivax
Adrenal Insufficiency;	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
Alanine Aminotransferase	Mycophenolate Mofetil			S	Unknown	1000 Milligram Daily;		Teva
Increased; Ascites;	Piperacillin Sodium /Tazobactam			S	Unknown			Not Reported
Asthenia; Blood Alkaline	Sodium							
Phosphatase Increased;	Prednisone			S	Unknown	10 Milligram Daily;		Actavis
Blood Bilirubin Increased;	Prednisone			S	Unknown			Actavis
Blood Potassium	Rosuvastatin Calcium			S	Unknown			Teva
Decreased; Blood	Vancomycin Hydrochloride			S	Unknown			Not Reported
Pressure Diastolic	Rituxan			S	Intravenous (not			Not Reported
Abnormal; Blood Pressure					otherwise specified)			
Increased; Congestive	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
Hepatopathy; Depression;	Sulfate]							
Diverticulitis; Endometrial	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
Disorder; Enterococcus	Sulfate]							
Test Positive; Fibrosis;	Ceftazidime			S	Unknown			Not Reported
Gamma-	Acetaminophen			C	Oral			Not Reported
Glutaryltransferase	Actonel			C				Not Reported
Increased; Gastrointestinal	Apo Amlo			C				Not Reported
Disorder; Generalised	Apo-K			C				Not Reported
Oedema; Heart Rate	Diphenhydramine Hydrochloride			C	Oral			Not Reported
Increased; Herpes Zoster;	Epoetin Alfa			C				Not Reported
Hypersensitivity;	Escitalopram			C	Unknown			Not Reported
Hypoglycaemia;	Hydrochlorothiazide			C				Not Reported
Hypotension; Increased	Ventolin [Salbutamol Sulfate]			C				Not Reported
Appetite; Influenza;	Tylenol [Paracetamol]			C				Not Reported
Infusion Related Reaction;	Slow-K			C				Not Reported
Injection Site	Risedronate			C				Not Reported
Extravasation; Intensive	Pantoprazole			C				Not Reported
Care Unit Acquired	Pantoloc [Pantoprazole]			C		40 Milligram Daily;		Not Reported
Weakness; Intervertebral	Metoprolol			C				Not Reported
Disc Protrusion; Joint	Methylprednisolone			C	Intravenous (not			Not Reported
Effusion; Joint Swelling;					otherwise specified)			
Micturition Disorder;	Metformin			C				Not Reported
Myelopathy; Myopathy;								
Nasopharyngitis; Nausea;								
Nerve Compression;								
Neuropathy Peripheral;								
Neutropenia;								
Osteoarthritis;								

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

Pancytopenia; Peripheral	Kcl	C	Not Reported
Sensorimotor Neuropathy;	Januvia	C	Not Reported
Peritonitis; Pneumonia;	Insulin Lispro	C	Not Reported
Pseudomonal	Hydroxychloroquine	C	Not Reported
Bacteraemia; Rheumatoid			
Arthritis; Septic Shock;			
Therapeutic Response			
Decreased; Vomiting;			
Weight Decreased; Weight			
Increased			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17205986	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA353135		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
Use; Rheumatoid Arthritis	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Arava			S	Oral	10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		300 Mg		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Methotrexate			S		12.5 Df		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Plaquenil			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S	Subcutaneous	25 Mg		Not Reported

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Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous	250 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
Rituximab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Bifidobacterium Bifidum	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Pantoprazole	C			Not Reported
Prednisone	C		40 Mg	Not Reported
Prednisone	C		250 Unk	Not Reported
Simponi	C			Not Reported
Sulfasalazine	C			Not Reported
Wellbutrin	C			Not Reported
Xeljanz	C	Oral	5 Mg	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C		200 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17211808	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA354607			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated;	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain;	Hydroxychloroquine			S				Sanofi
Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Plaquenil			S		200 Mg		Sanofi
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Mg Bid		Not Reported

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Sleep Disorder Due To General Medical Condition, Insomnia Type	Prednisone	S		20 Mg, Qd	Not Reported
	Prednisone	S		20 Mg, Qd	Not Reported
	Arava	S		10 Mg, Qd	Sanofi
	Sodium Aurothiomalate	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Bim	Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17215414	EXPEDITED (15-DAY)		OT	CA-SA-2019SA353952		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Visual Impairment	Sodium Aurothiomalate			S		Unk		Not Reported
	Sodium Aurothiomalate			S		Unk/Gold		Not Reported
	Arava			S	Oral	20 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

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

Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Depo-Medrol	C		Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Qw	Not Reported
Methotrexate	C	Unknown	15 Mg, Qw	Not Reported
Methotrexate	C	Subcutaneous	17.5 Mg	Not Reported
Methotrexate	C	Unknown	17.5 Mg	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Qw	Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Oral	1 G, Qd	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17427584	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1186381		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cryptosporidiosis	Hydroxychloroquine			S	Unknown			Teva	
Infection;	Methotrexate			S	Unknown			Barr	
Hypogammaglobulinaemia	Mycophenolate Mofetil			S	Unknown			Teva	
; Leukopenia;	Rituximab			S	Unknown			Not Reported	
Neutropenia; Weight Decreased									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17434479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019415671			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Finger Deformity; Foot Deformity; Gastrointestinal Disorder; Loss Of Personal Independence In Daily Activities; Nausea	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Parenteral	15 Mg, Unk		Not Reported
	Methotrexate			S	Parenteral	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported

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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17482799	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008186		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; C-Reactive Protein; Drug Intolerance; Fatigue; Finger Deformity; Gastrointestinal Disorder; Hypersensitivity; Nausea; Pain; Paraesthesia; Rheumatoid Arthritis; Swelling; Swollen Joint Count; Therapeutic Product Effect Incomplete; Urticaria	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Unknown	Unk, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Sarilumab			C	Unknown	Unk, Unknown		Not Reported
	Xeljanz			C	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17485926	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008204			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

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

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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543158	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022567		60 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram, Bid		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown	1 Gram, Bid		Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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

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

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

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

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

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Sulfate]									
Remicade		S	Intravenous (not otherwise specified)						Not Reported
Simponi		S	Subcutaneous						Not Reported
Sulfasalazine		S	Unknown						Not Reported
Acetaminophen		C	Unknown						Not Reported
Prednisone		C	Oral						Not Reported
Prednisone		C	Oral						Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Chills; Erythema; Fatigue; Hypotension; Klebsiella Infection; Leukopenia; Multiple Organ Dysfunction Syndrome; Odynophagia; Product Use Issue; Rash; Rash Vesicular; Skin Lesion; Thrombocytopenia; Varicella Zoster Virus Infection	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543235	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1364		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

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

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

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

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

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

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201880			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Fatigue; Feeling Abnormal; Therapeutic Response Decreased	Methotrexate			S	Unknown			Barr	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Leflunomide			C				Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543644	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022646			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Orencia			S	Unknown			Bristol Myers Squibb	
	Adalimumab			S	Subcutaneous			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Amitriptyline			C	Unknown			Not Reported	
	Cefazolin			C	Unknown			Not Reported	
	Clindamycin			C	Unknown			Not Reported	
	Prednisone			C	Unknown	10 Milligram		Not Reported	
	Tylenol W/Codeine No. 3			C	Unknown			Not Reported	
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543729	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202304		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Infection; Off Label Use; Pharyngeal Oedema; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Arava			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543733	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202183		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Epicondylitis; Myocardial Infarction; Pulmonary Fibrosis; Therapeutic Product Effect Decreased; Upper Limb Fracture	Methotrexate			S	Unknown			Barr	
	Celebrex			S	Unknown			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Unknown			Not Reported	
	Imuran			S	Unknown			Not Reported	
	Neoral			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not			Not Reported	

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543737	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202308		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Swelling; Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Response Decreased; Urinary Tract Infection	Methotrexate			S	Subcutaneous	3.5714 Milligram Daily;		Barr	
	Methotrexate			S	Subcutaneous	2.1429 Milligram Daily;		Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Desoximetasone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543813	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1202024			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness; Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia;	Methotrexate			S	Unknown			Barr	
	Acetylsalicylic Acid			S	Unknown			Not Reported	
	Acetylsalicylic Acid			S	Unknown			Not Reported	
	Acetylsalicylic Acid			S	Unknown			Not Reported	
	Diclofenac Potassium			S	Unknown			Actavis	
	Diclofenac Potassium			S	Unknown			Actavis	
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva	
	Sulfamethoxazole W/Trimethoprim			S	Unknown			Teva	
	Apo-Diclofenac			S	Topical			Not Reported	
	Arava			S	Unknown			Not Reported	

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Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold Sodium Thiomalate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naprosyn	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Voltaren	S	Unknown	Not Reported
	Tramadol Hydrochloride	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543832	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1201901			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis; Synovitis	Methotrexate			S	Unknown			Barr	
	Humira			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544307	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-020899		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amyotrophic Lateral Sclerosis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Q4wk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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Leflunomide	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544337	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567702		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544346	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567705			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567710		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported

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Xeljanz			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544665	NON-EXPEDITED			US-PFIZER INC-2020112039		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544958	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1026331		31 YR	Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Growth Restriction; Maternal Exposure During Pregnancy; Oligohydramnios; Premature Baby	Calcium Carbonate			S	Unknown	Unk		Not Reported	
	Omeprazole			S	Unknown	Unk		Unknown	
	Cefotaxime			S	Unknown	Unk		Mylan	
	Cefotaxime			S		Unk		Mylan	
	Privigen			S	Unknown	Unk		Mylan	
	Privigen			S		Unk		Mylan	
	Prednisone			S	Unknown	Unk		Mylan	
	Methylprednisolone			S	Unknown	Unk		Mylan	
	Dexamethasone			S		Unk		Mylan	
	Dexamethasone			S	Unknown	Unk		Mylan	
	Vitamin B Complex /04259401/			S	Unknown	Unk		Mylan	
	Cefixime			S	Unknown	Unk		Mylan	
	Metoprolol Tartrate			S	Unknown	Unk		Mylan	
	Bisoprolol Fumarate			S	Unknown	Unk		Mylan	
	Penicillin G /00000903/			S	Unknown	Unk		Mylan	
	Vulmizolin			S	Unknown	Unk		Mylan	

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Bisulepin	S	Unknown	Unk	Mylan
Ornidazole	S	Unknown	Unk	Mylan
Albumin	S	Unknown	Unk	Mylan
Aminomethylbenzoic Acid	S	Unknown	Unk	Mylan
Magnesium Lactate	S	Unknown	Unk	Mylan
Folic Acid	S	Unknown	Unk	Mylan
Nadroparin Calcium	S	Unknown	Unk	Mylan
Hydroxychloroquine	S	Unknown	Unk	Mylan
Vitamin D /00318501/	S	Unknown	Unk	Mylan
Hydrocortisone	S	Unknown	Unk	Mylan
Etamsylate	S	Unknown	Unk	Mylan
Flebogamma Dif /00025201/	S	Unknown	Unk	Mylan
Fluconazole	S	Unknown	Unk	Mylan
Potassium Chloride	S	Unknown	Unk	Mylan
Paracetamol	S	Unknown	Unk	Mylan
Vitamin K Nos	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544990	EXPEDITED (15-DAY)		OT	CA-SA-2017SA166761		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
Abdominal Discomfort;	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
Adverse Drug Reaction;	Arava			S	Oral	20 Mg, Qd		Sanofi
Adverse Drug Reaction;	Arava			S	Unknown	20 Mg, Qd		Sanofi
Anti-Cyclic Citrullinated Peptide Antibody; C- Reactive Protein	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
Increased;	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
Contraindicated Product	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
Administered; Drug	Orencia			S	Subcutaneous	Unk Unk,Unk		Not Reported
Ineffective; Drug								
Ineffective; Joint Swelling;								

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Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Orencia	S	Intravenous (not otherwise specified)	125 Mg, Qw	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Adalimumab	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	C	Subcutaneous	17.5 Mg,Unk	Not Reported
	Methotrexate	C	Subcutaneous	15 Mg,Qw	Not Reported
	Methotrexate	C	Unknown	17 Mg	Not Reported
	Methotrexate	C	Unknown	15 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	25 Mg, Qw	Not Reported
	Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
	Sulfasalazine	C	Oral	1 G,Qd	Not Reported
	Xeljanz	C	Oral	5 Mg,Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544993	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA210576		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Arava			S	Oral	10 Mg,Unk		Sanofi	

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Leflunomide	S			Sanofi
Leflunomide	S		20 Mg, Qd	Sanofi
Leflunomide	S		10 Mg Qd	Sanofi
Leflunomide	S		Unk	Sanofi
Sodium Aurothiomalate	S	Intramuscular	Unk Unk,Unk	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
Plaquenil	S		Unk Unk,Unk	Sanofi
Methotrexate	S		20 Mg, Qw, Solution	Not Reported
Methotrexate	S	Unknown	12.5 Df,Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, Bid	Sanofi
Hydroxychloroquine Sulfate	S		300 Mg	Sanofi
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Orencia	S	Subcutaneous	25 Mg	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	250 Mg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Unk	Not Reported
Rituxan	S		Unk	Not Reported
Gold	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S		50 Mg	Not Reported
Actemra	S			Not Reported
Actemra	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w	Not Reported
Prednisone	C	Unknown	40 Mg, For 3 Years	Not Reported
Prednisone	C	Unknown	250 Mg, For 7 Months	Not Reported

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Bifidobacterium Bifidum	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Sulfasalazine	C			Not Reported
Pantoprazole	C			Not Reported
Xeljanz	C	Oral	5 Mg	Not Reported
Simponi	C			Not Reported
Wellbutrin	C			Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17545125	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1026414			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Mabthera			S	Unknown	500 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Rituximab			S	Unknown	500 Mg, Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17545370	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020112214			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium	S	Unknown	Pfizer
	Xeljanz	S	Unknown	Pfizer
	Arava	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17545594	EXPEDITED (15-DAY)		OT	CA-SA-2019SA130822		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Arthralgia; Drug Ineffective; Headache; Joint Swelling; Pain In Jaw; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Meloxicam			S		15 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Atorvastatin Calcium			C		20 Mg		Not Reported
	Symbicort			C		Unk		Not Reported
	Gabapentin			C		100 Mg		Not Reported
	Lansoprazole			C		30 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546119	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1198500			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intestinal Haemorrhage	Hydroxychloroquine Sulfate Teva			S	Unknown			Teva

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546196	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020111601		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombophlebitis Superficial	Torvast			S				Pfizer	
	Paracetamol Alter			S	Oral	1 G, 1x/Day		Not Reported	
	Xarelto			S	Oral	20 Mg, 1x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546249	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA069998		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Ilaris			S	Subcutaneous	Unk		Novartis	
	Ilaris			S				Novartis	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S				Not Reported	
	Oxycodone			S	Unknown	10 Mg		Not Reported	
	Leflunomide			S	Oral	Unk		Not Reported	
	Leflunomide			S				Not Reported	
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulphate			S				Not Reported	
	Minocycline			S	Unknown	Unk		Not Reported	
	Minocycline			S				Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S				Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S				Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S				Not Reported	
	Arava			S	Unknown	Unk		Not Reported	

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Arava	S			Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S			Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S			Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Rituximab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546340	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3318751-00		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Humira			S	Subcutaneous			Not Reported	
Prescribed Underdose;	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Rheumatoid Arthritis;									
Therapeutic Product Effect Incomplete	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	

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Anakinra	S	Unknown	Not Reported
Apo Azathioprine	S	Unknown	Not Reported
Apo Leflunomide	S	Oral	Not Reported
Apo Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Azathioprine	S		Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S		Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S		Not Reported
Cimzia	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C		Not Reported
Codeine Phosphate	C		Not Reported
Altace	C		Not Reported
Apo Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C		Not Reported
Escitalopram	C		Not Reported
Citalopram Hydrobromide	C		Not Reported
Conjugated Estrogens	C		Not Reported
Cymbalta	C		Not Reported
Escitalopram	C		Not Reported
Estrace	C		Not Reported
Gabapentin	C		Not Reported

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Hydrochlorothiazide	C		Not Reported
Hydromorphone Hcl	C		Not Reported
Mupirocin	C	Topical	Not Reported
Pantoprazole	C		Not Reported
Shark Liver Oil	C		Not Reported
Tapentadol Hydrochloride	C		Not Reported
Taro Mupirocin	C	Topical	Not Reported
Tramacet	C	Oral	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546508	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021288		23 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546844	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA- 1202539		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Condition Aggravated; Diverticulitis;	Methotrexate			S	Unknown			Barr

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H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Chloroquine Diphosphate	S	Unknown	Not Reported
	Belimumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17546910	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202524		52 YR	Female	CAN

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

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17-Mar-2020	11624328	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1476711-00		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia;	Humira			S	Subcutaneous			Not Reported
Arthritis; Arthritis; Blood	Actemra			S	Unknown			Not Reported
Cholesterol Increased;	Arava			S	Unknown			Not Reported
Fibromyalgia; Herpes	Enbrel			S	Subcutaneous			Not Reported
Zoster; Infection;	Methotrexate			S	Unknown			Not Reported
Leukopenia; Liver	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Function Test Abnormal;	Plaquenil			S	Unknown			Not Reported
Peripheral Swelling;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Pneumonia Viral;								
Synovitis; Tenderness;	Xeljanz			S	Unknown			Not Reported
Tenderness; Therapeutic	Rituximab			S	Intravenous drip			Not Reported
Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Anakinra			C				Not Reported
	Ativan			C				Not Reported
	Benadryl			C				Not Reported
	Cortisone			C	Intramuscular			Not Reported
	Cortisone			C	Intra-arterial			Not Reported
	Dilaudid			C				Not Reported
	Enablex			C				Not Reported
	Lasix			C				Not Reported
	Leflunomide			C				Not Reported
	Loperamide			C				Not Reported
	Norflex			C				Not Reported
	Omniaris			C		Spray, Metered Dose		Not Reported
	Pantoprazole Sodium			C				Not Reported
	Rituxan			C	Intravenous (not otherwise specified)			Not Reported
	Vagifem			C	Vaginal			Not Reported

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Synthroid	C		Not Reported
Abatacept	C		Not Reported
Desoximetasone	C	Intra-arterial	Not Reported
Darifenacin	C		Not Reported

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17-Mar-2020	12696887	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 1453		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab Hospira			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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			otherwise specified)	
Remicade	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Infliximab	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Arava	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	12702886	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016087030		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Blood Glucose Increased;	Enbrel			S		Unk		Pfizer
Blood Pressure Increased;	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
C-Reactive Protein	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Abnormal; Condition	Enbrel			S	Unknown	40milligram, 4 Every 1 Week		Pfizer
Aggravated;	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Contraindicated Product	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Administered; Drug	Enbrel			S	Unknown	40 Milligram, Four Every One Week		Pfizer
Ineffective; Drug	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Intolerance; Fatigue;	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
Femur Fracture; Gait	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Disturbance; Gastric	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
Disorder; Glycosylated	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Haemoglobin Increased;	Enbrel			S	Unknown	50 Milligram, Qd		Pfizer
Heart Rate Increased;	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer
Hepatic Enzyme	Enbrel			S	Unknown	50 Milligram, Qwk		Pfizer

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Increased; Infection; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Enbrel	S	Unknown	Unk	Pfizer
Lymphocyte Count	Enbrel	S	Unknown	50 Milligram, 4 Every 1 Week	Pfizer
Increased; Malaise;	Sulfasalazine	S	Oral	2000 Mg, Unk	Pfizer
Musculoskeletal Stiffness;	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
Nasal Congestion;	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
Nasopharyngitis; Nausea;	Sulfasalazine	S	Oral	2000 Milligram, Unk	Pfizer
Neutrophil Count	Sulfasalazine	S	Oral	2000 Milligram, Qd	Pfizer
Increased; Off Label Use;	Sulfasalazine	S	Oral	1000 Milligram, Qd	Pfizer
Osteopenia; Pain; Pain In Extremity; Peripheral Swelling; Product Use	Sulfasalazine	S	Unknown	Unk	Pfizer
Issue; Pyrexia; Red Blood Cell Sedimentation Rate	Methotrexate Sodium	S	Subcutaneous	2.5 Mg/MI, Weekly	Pfizer
Increased; Red Cell Distribution Width	Methotrexate Sodium	S	Subcutaneous	Unk, Weekly (4 Every 1 Week)	Pfizer
Increased; Rheumatoid Arthritis; Somnolence;	Methotrexate Sodium	S	Unknown	Unk, Weekly	Pfizer
Synovitis; Tooth Abscess;	Methotrexate Sodium	S	Unknown	25 Df, Weekly	Pfizer
Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Methotrexate Sodium	S	Unknown	25 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Subcutaneous	20 Milligram, Qwk	Pfizer
	Arava	S	Oral	20 Mg, 1x/Day	Not Reported
	Arava	S		10 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Arava	S	Unknown	10 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Arava	S	Unknown	Unk Unk, Qd	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
	Plaquenil	S		200 Mg, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil	S	Unknown	200 Milligram, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported

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Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S		200 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	800 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	200 Milligram, Unk	Not Reported
Orencia	S	Unknown	200 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tylenol	S	Unknown	Unk	Not Reported
Hydroxychloroquine/Hydroxychlo	S	Oral	200 Milligram, Bid	Not Reported

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roquine Sulfate Hydroxychloroquine/Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	325 Mg, Unk	Not Reported
Acetaminophen	S	Unknown	325 Milligram	Not Reported
Acetaminophen	S	Oral	650 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	200 Mg, Bid	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S		Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Apo-Hydro	S		Unk	Not Reported
Apo-Hydro	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Apo Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Amaryl	S	Unknown	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Stelara	S	Unknown		Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Tylenol With Codeine No.3	C		Unk, As Needed	Not Reported

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Tylenol With Codeine No.3	C		Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Mg, 2x/Day	Not Reported
Celebrex	C		200 Milligram, Bid	Not Reported
Hydromorphone Hcl	C		Unk	Not Reported
Methotrexate	C	Unknown	Unk Unk, Weekly	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Methotrexate	C	Unknown	25 Dosage Form, Qwk	Not Reported
Methotrexate	C	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide (Micronized)	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Lipitor	C	Unknown		Not Reported
Metformin	C	Unknown	Unk Unk, Qd	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown		Not Reported
Ramipril	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Mg, Bid (2 Every 1 Days)	Not Reported
Xeljanz	C		50 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	12716207	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-		65 YR	Male	CAN

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

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Onychoclasia; Synovitis; Tooth Loss	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Zostavax			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

Apo Hydroxyquine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Diclofenac	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Cortisone Acetate	C	Unknown	Not Reported
Zostavax	C	Unknown	Not Reported
Voltaren	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	12933730	EXPEDITED (15-DAY)		DS, OT	CA-SA-2016SA201530		36 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical	Arava			S	Oral	10 Mg,Qd		Sanofi
	Sulfasalazine			S	Oral	500 Mg,Bid		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Prednisone			S	Unknown	20 Mg,Qd		Not Reported
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S		20 Mg		Not Reported

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

Condition, Insomnia Type	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Hydroxychloroquine	S		Unk	Sanofi
	Methotrexate [Methotrexate Sodium]	S	Subcutaneous	20 Mg, Unk	Not Reported
	Methotrexate [Methotrexate Sodium]	S		Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Orencia	S	Unknown	Unk Unk, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 G, Qcy	Not Reported
	Rituxan	S		2 Unk, Qcy	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2 G, Q6m	Not Reported
	Etanercept	S		50 Mg, Qw	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	13519996	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-038600			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosis	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Folic Acid			S	Unknown	5 Milligram		Not Reported	
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Apo-Prednisone			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Desoximetasone			S	Oral	Unk		Not Reported	

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

Enbrel	S	Unknown	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown		Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	13520451	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-039843		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported	
	Actemra			S	Unknown	8 Mg, Unk		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

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

	Methotrexate Sodium	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Cymbalta	C	Unknown		Not Reported
	Elavil [Amitriptyline Hydrochloride]	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Imitrex [Sumatriptan]	C	Unknown		Not Reported
	Lyrica	C	Unknown		Not Reported
	Premarin	C	Unknown		Not Reported
	Tenormin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Sumatriptan	C	Unknown		Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	13869108	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-2444		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	13869342	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017351180		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity;	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk, Weekly		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer

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

Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported
	Erythromycin	C		Unk	Not Reported
	Morphine	C	Topical	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	13870276	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2017350057			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Qwk		Not Reported
	Folic Acid			S	Unknown	5 Milligram, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Apo-Folic Acid			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	400 Mg, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Not Reported

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Cymbalta	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	13921480	EXPEDITED (15-DAY)	OT		CA-PFIZER INC-2017372781		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk (Prefilled Syringe)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid (1 Every 12 Hours)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

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

Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Imuran	C	Unknown	Unk	Not Reported
Arthrotec	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	14227055	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506816			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Qwk		Pfizer
	Actemra			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Arava			S	Unknown	20 Mg, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Meloxicam			S	Oral	7.5 Mg, Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	14227318	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017506298		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Enbrel			S	Unknown	50 Mg, Unk		Pfizer

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

Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Pfizer
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Pfizer
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	20 Mg, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	20 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	200 Mg, Bid	Not Reported
	Prednisone	S	Oral	5 Milligram, Qd	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	14230778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017510773		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	15 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	1 G, Qd		Pfizer
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Mg, Qd		Not Reported

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

Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	14570743	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2018- 0535		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Cystitis; Deformity; Depressed Mood; Encephalitis; Encephalitis Brain Stem; Fibromyalgia; Immunosuppression; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Peripheral Swelling; Product Use Issue; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Seizure; Sepsis; Spinal Deformity	Methotrexate (Trade Name Unknown) Enbrel Enbrel Celebrex Arava Actemra Actemra Plaquenil Apo-Prednisone Hydroxychloroquine Hydroxychloroquine Prednisone Dilaudid Lyrica Furosemide Hydromorph Contin			S S S S S S S S S S S S C C C C	Unknown Subcutaneous Unknown Unknown Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	14632418	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-020711		58 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Codeine			S	Unknown			Not Reported
	Fosamax			S	Unknown	70 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	25 Mg, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Unknown	12.5 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Mg, Qwk		Not Reported
	Methotrexate			S	Unknown	12 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown	680 Mg, Qmo		Not Reported
	Tocilizumab			S	Unknown	360 Mg, Qmo		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported

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

Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ciclosporin	S	Unknown	150 Milligram, Qd	Not Reported
Xeljanz	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qwk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15215485	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018305256		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Qwk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, 2 Times/Wk		Not Reported
	Actemra			S	Subcutaneous	162 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 3 Times/Wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Q2wk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, 2x/Week		Not Reported

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

Hydroxychloroquine	S	Unknown	400 Unk, Unk (Three In One Week)	Not Reported
Leflunomide	S		Unk	Not Reported
Prednisone	C	Unknown	20 Mg, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15246107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015106204		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Blood Cholesterol Increased; C-Reactive Protein	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
Abnormal; C-Reactive Protein Increased;	Enbrel			S		25 Mg, 2x/Day		Pfizer
Condition Aggravated; Contraindicated Product	Enbrel			S	Subcutaneous	25 Mg, Cyclic Q2wk		Pfizer
Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia;	Enbrel			S		25 Mg, (3 Years, Freq: 2 Week; Interval: 1)		Pfizer
Herpes Zoster; Infection; Joint Swelling;	Enbrel			S		25 Mg, Cyclic Q2wk		Pfizer
Leukopenia; Liver Function Test Abnormal;	Enbrel			S	Subcutaneous	25 Mg, Unk		Pfizer
Off Label Use; Oral Pain; Peripheral Swelling;	Xeljanz			S		Unk		Pfizer
Pneumonia Viral; Product Use Issue; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis;	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer
Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	25 Mg, 1x/Day		Pfizer
	Methotrexate Sodium			S	Vaginal	25 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S		25 Mg, 4 Times/Wk		Pfizer
	Methotrexate Sodium			S	Unknown	25 Mg, 11 Years, Freq: 1 Week; Interval: 1		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclic Every Two Weeks (Duration Reported As 365 Units Not Reported)		Not Reported

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

Humira	S	Unknown	200 Mg, 2x/Day	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	200 Mg, 2x/Day	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, Monthly, Therapy Duration Reported As 61 (Unit Not Reported), (Freq: 1 Month; Interval: 1)	Not Reported
Orencia	S		Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Plaquenil	S	Unknown	200 Mg, 2x/Day	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Monthly, Therapy Duration Reported As 184 (Unit Not Reported),	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine	S	Unknown	40 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	4 Mg, Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	40 Mg, Unk	Not Reported

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

Hydroxychloroquine Sulfate	S	Unknown	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Arava	S	Unknown	20 Mg, Daily	Not Reported
Arava	S		1 Mg, Every 1 Day	Not Reported
Arava	S		20 Mg, Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	1000 Mg, Day 1 &15	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	C	Intramuscular	Unk	Not Reported
Cortisone	C	Intra-articular	Unk	Not Reported
Benadryl	C		Unk, As Needed	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Lasix	C		40 Mg, 3x/Day	Not Reported
Lasix	C	Unknown	Unk	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk, As Needed	Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	1 G, Daily At Bedtime	Not Reported
Ativan	C		1 Mg,Every 1 Day	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Loperamide	C		2 Mg, 2x/Day	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk, 2x/Day	Not Reported
Norflex	C	Unknown	Unk, 2x/Day (Freq: 2 Day; Interval: 1)	Not Reported
Norflex	C		Unk	Not Reported

**FDA Adverse Event Reporting System
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Detailed Report**

Omnaris	C	Unknown	Unk (Spray, Metered Dose)	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Dilaudid	C		4 Mg, Qd	Not Reported
Dilaudid	C	Unknown	4 Mg, Every 6 Hours	Not Reported
Dilaudid	C		4 Mg, Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Abatacept	C		Unk	Not Reported
Leflunomide	C		Unk	Not Reported
Kineret	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C	Unknown	100 Mg, Unk	Not Reported
Anakinra	C		100 Mg, Unk	Not Reported
Furosemide	C	Unknown	40 Mg, Three Every One Day	Not Reported
Furosemide	C	Unknown	40 Mg, 3x/Week	Not Reported
Furosemide	C	Unknown	Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk (Freq: As Needed)	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported

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

Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Mg, Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Diphenhydramine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Oral	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Dyclone	C	Unknown	Unk	Not Reported
Kenalog	C	Intra-articular	40 Mg, Unk	Not Reported
Kenalog	C	Unknown	40 Milligram	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	C		Unk Unk, As Necessary (Freq: As Needed)	Not Reported
Plantago Ovata	C	Unknown	Unk	Not Reported
Dyclonine Hydrochloride	C		Unk	Not Reported
Orphenadrine [Orphenadrine Hydrochloride]	C	Unknown	1 Dosage Form, Bid	Not Reported
Pantoprazole Sodium	C		Unk	Not Reported
Pantoprazole	C		Unk	Not Reported
Triamcinolone Acetonide	C	Intra-articular	40 Milligram, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15357865	EXPEDITED (15-DAY)		HO	PHHY2018DK086994		47 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia Mycoplasmal	Azathioprine			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Insulin			C	Unknown	Unk (On Pump)		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15383851	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-082919			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Arthropathy; C- Reactive Protein	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Increased; Deformity;	Orencia			S	Unknown			Bristol Myers Squibb	
Disability; Drug Ineffective;	Abatacept			S	Unknown	Unk		Bristol Myers Squibb	
General Physical Health Deterioration; Infusion	Enbrel			S	Subcutaneous	15 Milligram, Qwk		Not Reported	
Related Reaction; Infusion	Enbrel			S	Subcutaneous	15 Milligram, Q2wk		Not Reported	
Site Reaction; Injection	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported	
Site Reaction; Intentional	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Product Use Issue; Joint Destruction; Joint Effusion;	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qmo		Not Reported	
Juvenile Idiopathic Arthritis; Mean Cell	Infliximab			S	Intravenous (not otherwise specified)	200 Milligram, Qwk		Not Reported	
Haemoglobin Decreased; Mean Cell Volume	Leflunomide			S	Oral	Unk		Not Reported	
Decreased; Mean Platelet Volume Decreased;	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported	
Monocyte Count Increased;	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported	
Musculoskeletal	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported	
Deformity; Off Label Use;	Rituximab			S	Intravenous (not otherwise specified)	420 Milligram		Not Reported	
Osteoarthritis; Pain;	Rituximab			S	Unknown			Not Reported	
Physical Disability; Platelet Count Increased; Product Dispensing Error; Product	Sulfasalazine			S	Unknown	Unk		Not Reported	
Use Issue; Red Blood Cell Sedimentation Rate	Tocilizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Abnormal; Red Blood Cell Sedimentation Rate	Tocilizumab			S	Unknown			Not Reported	
Increased; Red Cell Distribution Width	Actemra			S	Unknown	Unk		Not Reported	
Decreased; Red Cell Distribution Width	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
Increased; Rheumatoid Arthritis; Treatment									

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Failure; Vascular Access Complication; White Blood Cell Count Increased	Adalimumab	S	Subcutaneous	40 Milligram, Qwk	Not Reported
	Adalimumab	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous	15 Milligram, Q2wk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15617576	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555631-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Ill-Defined Disorder; Injection Site Reaction	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			C				Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15619140	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555653-00		43 YR	Female	CAN

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

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Xeljanz			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15619319	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2554744-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lipitor			C	Oral			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15619584	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2555197-00		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Cerebrovascular Accident; Contraindicated Product Administered; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Leflunomide Apotex			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Aspirin	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15620413	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555889-00		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15621393	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557319-00		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15627588	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2559128-00		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Pain; Synovitis	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Naproxen			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported	
	Plaquenil			S	Oral			Not Reported	

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

Naproxen Sodium	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Risedronate	C	Oral	Not Reported
Arava	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15660935	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016545757		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Enbrel			S		50 Mg, Weekly		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S		4 Years		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Prednisone			C		10 Mg, 1x/Day		Not Reported
	Coversyl [Perindopril Erbumine]			C		Unk		Not Reported
	Hydroxychloroquine			C				Not Reported
	Cephalexine			C	Unknown	500 Milligram, Qid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15710031	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015280551		41 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Enbrel	S	Subcutaneous	Unk	Pfizer
	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15720388	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2017364037		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Enbrel			S	Unknown	50 Milligram		Pfizer
Arthralgia; Contraindicated	Enbrel			S	Unknown	Unk		Pfizer
Product Administered;	Etanercept			S	Unknown	Unk		Pfizer
Drug Ineffective;	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Pfizer
Dyspepsia; Fatigue;	Minocin			S	Unknown	Unk		Pfizer
Gastric Disorder; General	Minocycline Hcl			S	Unknown	Unk		Pfizer
Physical Health	Salazopyrin			S	Unknown	Unk		Pfizer
Deterioration; Joint	Methotrexate Sodium			S	Unknown	Unk		Pfizer
Swelling; Malaise;	Methotrexate Sodium			S	Unknown	15 Milligram, Qwk		Pfizer
Nausea; Off Label Use;	Methotrexate Sodium			S	Oral	Unk		Pfizer
Pain; Product Use In	Simponi			S	Subcutaneous	Unk		Not Reported
Unapproved Indication;	Simponi			S	Unknown	Unk		Not Reported
Rash; Rheumatoid								
Arthritis; Sleep Disorder								

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

Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Subcutaneous	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Subcutaneous	Unk	Not Reported
Myochrysine	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported

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

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Abatacept	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15781901	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017013508		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Enbrel			S		25 Mg, 2x/Week		Pfizer
	Enbrel			S	Unknown	25 Mg, Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Apo-Leflunomide			S	Oral	20 Mg, Daily		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Unknown	300 Mg, Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S		200 Mg, 2x/Day		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

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

Rituxan	S	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk
Actemra	S	Unk	Not Reported
Actemra	S	Unknown	Unk
Anakinra	S	Unknown	Unk
Leflunomide	S	Unknown	20 Mg, Qd
Apo-Hydroxyquine	S	200 Mg, Bid	Not Reported
Hydroxychloroquine Sulfate	S	200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk
Arava	S	Unknown	Unk
Rituximab	S	Unknown	1 Gram
Wellbutrin	C	Unknown	Unk
Sulfasalazine	C	1 G, 2x/Day	Not Reported
Xeljanz	C	Unknown	Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15851696	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633984-00		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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

Tocilizumab	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15926889	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651972-00		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Tablet		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

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

Plaquenil	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz Xr	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15934368	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2655903-00		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Rheumatoid	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Benzalkonium Chloride			S	Unknown			Not Reported
	Boric Acid			S	Unknown			Not Reported
	Disodium Edetate			S	Unknown			Not Reported
	Phenylephrine Hydrochloride			S	Unknown			Not Reported
	Sodium Borate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Rho D Immune Globulin	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Celebrex	C	Oral	Not Reported
	Ibuprofen	C	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Methotrexate	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15953507	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-012131		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	

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

	Apo-Leflunomide	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	15995703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2674768-00		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Vaginal	Dosage Form Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Enablex			C	Unknown			Not Reported

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

Lasix	C	Unknown		Not Reported
Loperamide	C			Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray, Metered Dose	Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Synthroid	C	Unknown		Not Reported
Vagifem	C	Unknown		Not Reported
Pantoloc	C		(Enteric Coated)	Not Reported
Darifenacin Hydrobromide	C			Not Reported
Desoximetasone	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16075583	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-012946		14 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Intentional Product Use Issue; Lymphoproliferative Disorder; Off Label Use; Off Label Use Of Device; Product Use In Unapproved Indication; Renal Cell Carcinoma	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Metformin Tablet			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Enalapril Maleate			S	Unknown	Unk		Not Reported
	Ferrous Fumarate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	100.0 Milligram, 1 Every 1 Month		Not Reported
	Infliximab			S	Unknown	1000.0 Milligram, 1 Every 1 Month		Not Reported
	Infliximab			S				Not Reported
	Insulin			S	Unknown	Unk		Not Reported

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

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S			Not Reported
Nutropin	S	Subcutaneous	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Ranitidine	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Androderm	S	Unknown	Unk	Not Reported
Protopin	S	Intramuscular	Unk	Not Reported
Acetazolamide	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S			Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S			Not Reported
Insulin Human	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16332181	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019210438			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Hyperhidrosis; Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Estradot			S	Transdermal	Unk, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16334554	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018103158		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Enbrel			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Xeljanz			S	Oral	5 Milligram, Bid		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	10 Milligram		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, (1 Every 2 Week(S))		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sarilumab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported

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

Apo-Leflunomide	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported
Prednisone	C		10 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16343860	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019217974			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Milligram, Qwk		Pfizer
	Sulfasalazine			S	Unknown	2 Gram, Qd		Pfizer
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Xeljanz			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16387751	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-050993		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Rituximab			S	Intravenous drip			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

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

Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Humira	S	Unknown	200 Milligram, Bid	Not Reported
	Humira	S	Unknown	1 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Vagifem	C	Vaginal		Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Qmo	Not Reported
	Arava	S	Unknown	20 Milligram, Qd	Not Reported
	Ativan	C	Unknown	1 Gram	Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Oral		Not Reported
	Dilaudid	C	Unknown	4 Milligram	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported
	Furosemide	C	Unknown	40 Milligram, 3 Times/Wk	Not Reported
	Loperamide	C	Unknown	Unk, Bid	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Unk, Bid	Not Reported
	Omnaris	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Anakinra	C	Unknown	100 Milligram	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Darifenacin Hydrobromide	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported

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

Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Milligram	Not Reported
Lasix [Furosemide]	C	Unknown	Unk	Not Reported
Morphine Sulfate	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Leflunomide	C	Unknown		Not Reported
Desoximetasone	C	Intramuscular		Not Reported
Desoximetasone	C	Intra-arterial		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16600726	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068199		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Joint Swelling; Off Label Use; Pain; Pemphigus; Rash;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Orencia			S	Subcutaneous			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Oral			Not Reported	

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

Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	50 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk Unk, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Hydrocortisone Acetate	S	Cutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16691316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2885135-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Contraindicated Product Administered; Drug Ineffective	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16802106	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019396164		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Enbrel			S		50 Mg, Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Ergocalciferol			C		Unk, Weekly		Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C		Unk, 2x/Day		Not Reported
	Estrogel			C		0.6 %, 3x/Day		Not Reported
	Furosemide			C		40 Mg, 1x/Day		Not Reported

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

Morphine	C	Unknown	Unk	Not Reported
Potassium Chloride	C	Unknown	1500 Mg, 1x/Day	Not Reported
Valsartan	C		320 Mg, 1x/Day	Not Reported
Xalatan	C		50 Ug, 1x/Day	Not Reported
Zingiber Officinale	C	Oral	500 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16817883	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019399548			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	20 Mg, 1x/Day		Pfizer
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Orencia			S	Unknown	750 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Gold			S	Unknown	50 Milligram		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16830577	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27321			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abdominal Pain; Condition Aggravated;	Infliximab	S	Unknown	Unknown	Not Reported
Contraindicated Product Administered; Drug	Enbrel	S	Unknown	Unknown	Not Reported
Intolerance; Headache; Nausea; Off Label Use;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Morphine	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17033629	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019493322			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Pantoprazole			S	Unknown	Unk		Pfizer
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Infliximab Hospira			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Morphine Sulfate			S	Unknown	Unk		Pfizer
	Morphine Hydrochloride			S	Unknown	Unk		Not Reported
	Cefixime			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			S	Oral	100 Milligram		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17215587	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-		36 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Simponi			S	Unknown	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Calcium			C	Unknown			Not Reported
	Dorzolamide			C	Unknown	Unknown		Not Reported
	Hydrochloride/Timolol Maleate							
	Dorzolamide			C	Unknown	Unknown		Not Reported
	Hydrochloride/Timolol Maleate							
	Ergocalciferol			C	Unknown	Unknown		Not Reported

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Ergocalciferol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown	Unknown	Not Reported
Estradiol	C	Unknown		Not Reported
Furosemide	C	Unknown		Not Reported
Gravol Ginger	C	Unknown		Not Reported
Morphine	C	Unknown	Unknown	Not Reported
Potassium Chloride	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Xalatan	C	Unknown		Not Reported
Xalatan	C	Ophthalmic	Solution Ophthalmic	Not Reported
Xeljanz	C	Oral		Not Reported
Zingiber Officinale	C	Oral		Not Reported
Estrogel	C	Unknown		Not Reported
Estrogel	C	Unknown		Not Reported
Baclofen	C	Unknown		Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Gravol Ginger Nighttime	C	Unknown	Unknown	Not Reported
Levaquin	C	Unknown		Not Reported
Tofacitinib Citrate	C	Oral		Not Reported
Acetaminophen	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17283605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP005143		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Doxycycline			S	Unknown	50 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Prednisone			S	Oral	5 Mg, Bid		Not Reported

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Prednisone	S	Oral	5 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk (Once In 4 Weeks)	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	Unk Unk, Q.Wk.	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Folic Acid	C	Unknown	5 Mg, Unk	Not Reported
Naproxen	C	Unknown	500 Mg, Bid	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17390882	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018169790		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use	Enbrel			S		50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer
	Enbrel			S		50 Mg, 1x/Day		Pfizer
	Sulfasalazine			S	Oral	1 G, 2x/Day		Pfizer
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ciclosporin			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

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Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Leflunomide	S		Unk	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Methotrexate Sodium	C		25 Mg, Weekly	Not Reported
Hydroxychloroquine	C		200 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17422939	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-010154		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported	
	Enbrel			S	Unknown	25 Milligram, 2 Every One Week		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every One Day		Not Reported	
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported	

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Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
Remicade	S	Unknown	300 Milligram, Q6wk	Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17440627	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016346047		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Enbrel			S	Unknown	Unk		Pfizer
Alopecia; Chest Pain;	Enbrel			S	Unknown	Unk		Pfizer
Contraindicated Product	Enbrel			S	Unknown	Unk		Pfizer
Administered; Discomfort;	Methotrexate Sodium			S	Oral	Unk		Pfizer
Drug Hypersensitivity;	Methotrexate Sodium			S	Unknown	25 Milligram (1 Every 24 Hours)		Pfizer
Drug Ineffective; Duodenal	Methotrexate Sodium			S	Unknown	25 Milligram (1 Every 24 Hours)		Pfizer
Ulcer Perforation;	Methotrexate Sodium			S	Unknown	Unk		Pfizer
Dyspnoea; Fatigue;	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
Glossodynia; Hand	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
Deformity; Helicobacter	Sulfasalazine			S	Oral	500 Milligram		Pfizer
Infection; Hepatic Enzyme	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
Increased;	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
Hypersensitivity; Infusion	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
Related Reaction;	Sulfasalazine			S	Oral	1 Gram, Bid		Pfizer
Maternal Exposure During	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
Pregnancy; Pain;	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
Pemphigus; Pericarditis;	Tofacitinib Citrate			S	Unknown	5 Milligram, Bid		Pfizer
Product Use Issue; Rash;	Plaquenil			S	Unknown	Unk		Not Reported
Rheumatoid Arthritis;	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
Swelling; Synovitis;	Plaquenil			S	Oral	400 Milligram, Qd		Not Reported
Systemic Lupus	Arava			S	Oral	Unk		Not Reported
Erythematousus; Therapy	Arava			S	Oral	Unk		Not Reported
Non-Responder;	Arava			S	Oral	Unk		Not Reported
Treatment Failure; Wound	Cimzia			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

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

Orencia	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S		Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Atasol [Paracetamol]	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S		Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Oral	500 Milligram	Not Reported
Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported

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	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Vitamin C	C		Unk	Not Reported
	Vitamin D	C		Unk	Not Reported
	Alaskan Salmon Oil	C		Unk	Not Reported
	Glucosamine	C		Unk	Not Reported
	Lansoprazole	C		30 Mg, 2x/Day	Not Reported
	Ativan	C		2 Mg, 3x/Day, As Needed	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17547396	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-059951			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Cefixime			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk		Not Reported
	Imuran			S	Oral	100 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Morphine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rivotril			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zopiclone			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17547515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568992			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17547563	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201804-001263			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Pneumonia	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Salazopyrin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

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Pantoprazole	C		Not Reported
Methotrexate	C	Unk	Not Reported
Loperamide	C	Unk	Not Reported
Celebrex	C	Unk	Not Reported
Bifidobacterium Bifidum	C	Unk	Not Reported
Align	C	Unk	Not Reported
Actemra	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17547565	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201804-001261			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Leflunomide			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Bifidobacterium Bifidum			C		Unk		Not Reported
	Loperamide			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17547716	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201805-001646			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Hypersensitivity; Drug Ineffective; Drug Intolerance	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil Silver	S	Oral	Unk, Tablet	Concordia
	Sulfadiazine	S	Oral	Unk	Not Reported
	Naprosyn	S	Unknown	Unk	Not Reported
	Penicillin G Sodium	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Weekly	Not Reported
	Desoximetasone	C		Unk	Not Reported
	Hydroxychloroquine	C		Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Tylenol [Paracetamol]	C		Unk	Not Reported
	Cortisone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17547762	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- GSH201804-001274			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	Unk		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk, Subcutaneous Solution		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Weekly		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Novo-Rythro			S	Unknown	Unk		Not Reported

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Risedronate Sodium	S	Oral	35 Mg, Weekly	Not Reported
Marijuana	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Celebrex	C		Unk	Not Reported
Ergocalciferol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023061		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548119	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1391			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

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Arava	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548364	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568773			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568775			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported

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

Xeljanz			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548444	EXPEDITED (15-DAY)		OT	NVSC2020CA073084		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis	
	Neoral			S	Oral	Unk		Novartis	
	Cyclosporine			S	Unknown	Unk		Novartis	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported	
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported	
	Methotrexate			S	Oral	20 Mg		Not Reported	
	Methotrexate			S	Oral	20 Mg		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	1 Df, Qw		Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Oral	Unk		Not Reported	
	Orencia			S	Subcutaneous	125 Mg		Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	3 Mg		Not Reported	
	Rituxan			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral	Unk		Not Reported	
	Xeljanz			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548451	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567814		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous drip			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Imuran [Azathioprine]			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203461			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hypersensitivity; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Kevzara			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Acetaminophen			C	Unknown	1300 Milligram Daily;		Not Reported	
	Atacand			C	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Hydrodiuril			C	Unknown			Not Reported	

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	Kevzara	C	Unknown		Not Reported
	Neurontin	C	Unknown	1800 Milligram Daily;	Not Reported
	Premarin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548476	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203253			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Methotrexate			S	Unknown	2.8571 Milligram Daily;		Barr	
	Adalimumab			S	Subcutaneous			Not Reported	
	Arava			S	Unknown	20 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Calcium			C				Not Reported	
	Fentanyl			C				Not Reported	
	Folic Acid			C				Not Reported	
	Magnesium			C				Not Reported	
	Naproxen Sodium			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Potassium			C				Not Reported	
	Tramadol			C				Not Reported	
	Vitamin D[Colecalciferol]			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548477	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203601		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis	Methotrexate			S	Unknown			Barr	
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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Xalatan	S	50 Microgram Daily;	Not Reported
Actemra	S	Unknown	Not Reported
Dorzolamidedhydrochloride/Timolol Maleate	C		Not Reported
Ergocalciferol	C		Not Reported
Estrojel	C	1.8 Percent Daily;	Not Reported
Furosemide	C	40 Milligram Daily;	Not Reported
Morphine	C		Not Reported
Potassium Chloride	C	1500 Milligram Daily;	Not Reported
Valsartan	C	320 Milligram Daily;	Not Reported
Zingiber Officinale	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203488			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosis	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

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Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Topicort	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548712	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203265			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Methotrexate			S	Unknown			Barr	
	Adalimumab			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Tylenol Arthritis Pain 8h			C				Not Reported	
	Desoximetasone			C		20 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203616		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Methotrexate			S	Subcutaneous			Barr	
	Anakinra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Arava			S	Unknown	20 Milligram Daily;		Not Reported	
	Arava			S	Unknown	10 Milligram Daily;		Not Reported	
	Arava			S	Unknown	10 Milligram Daily;		Not Reported	
	Meloxicam			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548868	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203538			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17549106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204060		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17549539	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR042663			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Product Use Issue; Toxicity To Various Agents	Benlysta			S		Unk		Glaxosmithkline	
	Plaquenil			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17549774	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2020-012083		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Reconstitution Inflammatory Syndrome; Neutrophilia; Whipple'S Disease	Methylprednisolone			S	Unknown	Unk		Aurobindo	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Cyclobenzaprine			C	Unknown	Unk		Not Reported	
	Celecoxib			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17550494	NON-EXPEDITED			NVSC2020US075268		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis	
	Prednisone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17550624	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021775			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Drug-Induced	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb	

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Liver Injury; Headache	Azathioprine	S	Unknown	150 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	200 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous	15 Milligram, Qwk	Not Reported
	Sulfasalazine	C	Unknown	500 Milligram, Q12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17550986	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08585		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous, Single-Use Pre-Filled Syringe		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution, Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported

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Humira	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Simponi	S	Unknown	Unknown, Solution, Subcutaneous	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17551371	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021283			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Orencia			S	Unknown			Bristol Myers Squibb	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Enbrel			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17551480	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		52 YR	Male	CAN

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BMS-2020-023095

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17551711	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021350		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			C	Unknown	0.8 Milliliter		Not Reported
	Xeljanz			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552311	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021309		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb	
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Humira			C	Unknown			Not Reported	
	Celebrex			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204244		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Methotrexate			S	Unknown			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S	Unknown			Not Reported	

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

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Warfarin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552337	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1204372		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Circumstance Or Information Capable Of Leading To Medication Error; Condition Aggravated; Intervertebral Discitis; Pyrexia; Synovitis; Transaminases Increased	Methotrexate			S	Unknown			Barr
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552354	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1203747			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Cell Carcinoma	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552356	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204264			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug	Methotrexate			S	Unknown	20 Milligram Daily;		Barr

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Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552357	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204242		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552382	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1204376		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cardiac Failure	Methotrexate	S	Subcutaneous		Barr
Congestive; Hypertensive	Arava	S	Oral		Not Reported
Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3324326-00		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Haemophilus Influenzae			C		Vaccine		Not Reported
	Prevnar 13			C	Intramuscular			Not Reported
	Tetanus Vaccine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552708	EXPEDITED (15-DAY)		OT	NVSC2020CA073106		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported

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Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported

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Xeljanz			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17552911	EXPEDITED (15-DAY)		OT	NVSC2020CA071955		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Unknown	Unk		Novartis	
	Neoral			S	Subcutaneous	Unk		Novartis	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8.0 Unk		Not Reported	
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported	
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Oral	20 Mg		Not Reported	
	Methotrexate			S	Oral	20 Unk		Not Reported	
	Orencia			S	Subcutaneous	125 Mg		Not Reported	
	Remicade			S	Unknown	3 Mg		Not Reported	
	Sulphasalazine			S	Oral	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Xeljanz			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17553141	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027175			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Disease Recurrence; Drug Ineffective	Prednisone	S	Unk	Not Reported
	Hydroxychloroquine	S	200 Milligram, Qd For 3 Months	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	13816053	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017329621		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Enbrel			S	Subcutaneous	1 Dosage Form, Qwk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Enbrel			S	Subcutaneous	Unk, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Arava			C		Unk		Not Reported
	Codeine			C	Unknown	Unk		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

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Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	13856372	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-070330			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qd		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	13929661	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017- 2691		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

Therapeutic Product Effect	Plaquenil	S	Unknown	Not Reported
Decreased; Weight	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14447073	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043369		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Arava			S	Oral	Unk		Sanofi
Arthropathy; Arthropathy;	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
Condition Aggravated;	Plaquenil			S	Oral	Unk		Sanofi
Condition Aggravated;	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
Contraindicated Product	Methotrexate			S	Unknown	Unk		Not Reported
Administered; Drug	Rocuronium Bromide			S	Unknown	Unk Unk,Unk		Not Reported
Hypersensitivity; Drug	Rocuronium Bromide			S	Unknown	Unk		Not Reported
Ineffective; Finger	Codeine			S	Unknown	Unk Unk,Unk		Not Reported
Deformity; Finger	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
Deformity; Limb	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Unk		Sanofi
Operation; Off Label Use;	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
Pain; Peripheral Swelling;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
Peripheral Swelling; Rash;	Benzylpenicillin Sodium			S	Unknown	Unk Unk, Unk		Not Reported
Swelling; Tendon	Phenoxymethylpenicillin			S	Unknown	Unk		Not Reported
Disorder; Tendon	Potassium			S	Unknown	Unk Unk, Unk		Not Reported
Operation; Tenosynovitis;	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk,Unk		Not Reported
Treatment Failure;	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
Urticaria; Urticaria; Wrist	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
Surgery								

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

Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Gold	S	Unknown	Unk Unk, Unk	Not Reported
Rituximab	S		Unk	Not Reported
Prednisone	C	Unknown	Unk Unk,Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14570820	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0542		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Hepatic Enzyme Increased; Liver Function Test Increased; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14630900	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP007493		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased;	Apo-Prednisone	S	Unknown	Unk	Apotex
Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematous; Wound	Cetirizine	S	Unknown	10 Mg, Unk	Apotex
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Qd	Apotex
	Hydroxychloroquine	S	Oral	Unk	Apotex
	Prednisone	S	Oral	Unk (Therapy Duration 365 Unit Unspecified)	Apotex
	Apo-Hydroxyquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Diclofenac Sodium	S	Unknown	Unk	Apotex
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unit Unspecified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk (Therapy Duration: 365 Unspecified Unit)	Not Reported

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

Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid (Therapy Duration 365 Unit Unspecified)	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	10 Mg, Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14634899	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-0737		59 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Hypersensitivity; Drug Ineffective; Drug	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Intolerance; Headache; Rheumatoid Arthritis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Therapeutic Product Effect Incomplete; Tremor	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

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

Sulfasalazine	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Pantoprazol Sodium	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Tenofovir	C	Unknown	Not Reported
Pantoprazol	C	Unknown	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported
Pantoprazole Sodium	C	Unknown	Not Reported
Pantoprazole Bluefish	C	Unknown	Not Reported

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

Pantoprazole

C

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14788664	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018- 1170			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14836032	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018- 1328		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown	2x/Week		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15242994	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 1069		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Product Use Issue; Rash; Skin Mass; Therapy Non-Responder	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Prednisone Acetate	S	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15243408	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 0441		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthralgia;	Methotrexate (Trade Name			S	Unknown			Not Reported
Bronchitis; C-Reactive	Unknown)							
Protein Increased; Colitis	Methotrexate (Trade Name			S	Unknown			Not Reported
Microscopic;	Unknown)							
Contraindicated Product	Enbrel			S	Unknown			Not Reported
Administered;	Enbrel			S	Unknown			Not Reported
Diverticulitis; Drug	Sulfasalazine			S	Unknown			Not Reported
Ineffective; Drug	Infliximab			S	Unknown			Not Reported
Intolerance; Glaucoma;	Cimzia			S	Subcutaneous			Not Reported
Hepatic Enzyme	Cimzia			S	Unknown			Not Reported
Increased;	Orencia			S	Unknown			Not Reported
Hypersensitivity;								
Hypertension; Limb								
Discomfort; Pneumonia;								

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

Skin Reaction; Synovitis; Thyroid Disorder; Thyroxine Decreased; Treatment Failure; Vomiting	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Methadone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Xalatan	C	Unknown	Not Reported
	Cosopt	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Jampk20	C	Unknown	Not Reported
	Dorzolamide Hcl/Timolol Maleate	C	Unknown	Not Reported
	Baclofen	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported

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

Zingiber Officinale	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Cortisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Estradiol	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15293692	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 1469		55 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown) Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15621032	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557288-00		56 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Photosensitivity Reaction; Stomatitis; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Oxycodone			S	Unknown	Cr Tablet		Not Reported
	Enbrel			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			C				Not Reported
	Enbrel			C				Not Reported
	Leflunomide			C				Not Reported
	Lyrica			C	Oral			Not Reported
	Oxycodone			C				Not Reported
	Sulfasalazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15622638	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557282-00		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased;	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified) Powder For Solution Intravenous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15622672	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557461-00		23 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective; Rheumatoid Arthritis	Humira	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15622680	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2557508-00		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthropathy; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Musculoskeletal Disorder; Skin Warm	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

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

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15624172	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556726-00		57 YR	Male	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15721414	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1025		41 YR	Male	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Loss Of Personal Independence In Daily Activities; Nodule; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15855189	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2017546580		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	50 Mg, 2x/Day		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Tofacitinib Citrate			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qwk		Pfizer
	Kevzara			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every 10 Days		Not Reported

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

Humira	S	Subcutaneous	40 Milligram, Q (Every)14 Day	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	50 Milligram, Q4wk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	200 Milligram, Bid	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
Adalimumab	S	Unknown	40 Milligram, 1 Every 14 Days	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	750 Milligram, Q4wk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not	1 Gram	Not Reported

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

Rabeprazole Sodium		C		otherwise specified) Oral		20 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15956472	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190209141		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Arthritis; Bone Erosion; C-Reactive Protein Increased; Crohn'S Disease; Decreased Appetite; Drug Ineffective; Drug Intolerance; Exostosis; Fatigue; Foot Deformity; Hepatic Cirrhosis; Hypoaesthesia; Joint Dislocation; Joint Stiffness; Malaise; Mobility Decreased; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Rash; Red Blood Cell Sedimentation Rate Increased; Retinitis; Rheumatoid Arthritis; Synovitis; Visual Impairment	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Stelara			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Otezla			S	Oral			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Etanercept			S	Unknown			Not Reported	

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

Methotrexate	S	Oral	Not Reported
Minocycline	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Sirukumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported
Bupropion Hydrochloride	C		Not Reported
Hydromorphone Hydrochloride	C		Not Reported
Bupropion	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16075445	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-012854		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week		Aurobindo
Aminotransferase; Aspartate	Alendronic Acid			S	Unknown	70 Milligram, Every Week		Aurobindo
Aminotransferase; Aspartate	Alendronic Acid			S	Unknown	Unk		Aurobindo
Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	2.68 Milligram, 1 Every 4 Weeks		Not Reported
	Actemra			S	Unknown	680.0 Milligram, 1 Every 1 Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every Week		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Every Week		Not Reported

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

Skin; Hypercalcaemia;	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
Hypersensitivity;	Enbrel	S	Unknown	25.0 Milligram, 1 Every 2 Weeks	Not Reported
Inflammation; Infusion					
Related Reaction; Loss Of					
Personal Independence In	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
Daily Activities;					
Musculoskeletal Stiffness;	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Pain; Panniculitis;					
Peripheral Swelling;	Leflunomide	S	Unknown	Unk	Not Reported
Product Use Issue; Rash;	Leflunomide	S	Unknown	20 Milligram	Not Reported
Rash Pruritic; Red Blood	Leflunomide	S	Oral	Unk	Not Reported
Cell Sedimentation Rate					
Increased; Rheumatoid	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
Arthritis; Rheumatoid	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
Nodule; Skin Necrosis;					
Skin Ulcer; Therapeutic	Methotrexate	S	Unknown	12 Milligram	Not Reported
Product Effect Decreased;					
Therapeutic Response	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Decreased; Ulcer					
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 2 Weeks	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, 1 Every 4 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every 4 Weeks	Not Reported

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

Methotrexate	S	Unknown	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Every Week	Not Reported
Methotrexate	S	Oral	10.0 Milligram, 1 Every 4 Weeks	Not Reported
Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
Orencia	S	Unknown	760 Milligram, 1 Every 1 Week	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Unknown	150 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 1 Month	Not Reported
Myochrysine	S	Parenteral	50.0 Milligram, 1 Every 1 Month	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2 Every 1 Day	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Month	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680.0 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported

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

Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	15.5milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	17.5milligram, 1 Every 1 Week	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	10 Milligram, 1 Every 1 Day	Not Reported
Xeljanz	C	Unknown	5 Milligram, 2 Every 1 Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16075451	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012895		58 YR	Female	CAN

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every 1 Week(S)		Aurobindo
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, 1 Every 2 Week(S)		Not Reported
	Humira			S	Unknown	40 Milligram, 1 Every 1 Week(S)		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram		Not Reported
	Methotrexate			S	Oral	10 Milligram, 1 Every 1 Week(S)		Not Reported
	Methotrexate			S	Unknown	12 Milligram, 1 Every 1 Week(S)		Not Reported
	Orencia			S	Unknown	78 Milligram, 1 Every 1 Week(S)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Unknown	1000 Milligram, 2 Every 1day(S)		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	680 Milligram, 1 Every 1month(S)		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every 1month(S)		Not Reported

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Methotrexate	S	Subcutaneous	10 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, 1 Every Week (S)	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	50 Milligram, Once A Day	Not Reported
Methotrexate	S	Subcutaneous	780 Milligram, Once A Day	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	10 Milligram, 1 Every Week (S)	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Milligram, 1 Every 1 Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16080822	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-012964			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; C-Reactive Protein Increased;	Celecoxib Capsules			S	Unknown	Unk		Aurobindo	
Cataract; Contraindicated	Actemra			S	Unknown	Unk		Not Reported	
Product Administered;	Arava			S	Unknown	Unk		Not Reported	
Drug Ineffective; Hepatic	Enbrel			S	Unknown	Unk		Not Reported	
Cirrhosis; Knee	Humira			S	Subcutaneous	Unk		Not Reported	
Arthroplasty; Loss Of	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
Personal Independence In	Methotrexate			S	Oral	Unk		Not Reported	
Daily Activities;	Orencia			S	Unknown	Unk		Not Reported	
Rheumatoid Arthritis	Remicade			S	Intravenous (not	Unk		Not Reported	

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

			otherwise specified)		
	Celebrex	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, 2 Every 1 Week	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	2 Milligram, Once A Day	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16081413	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-013665		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Incorrect Route Of Product Administration; Infection; Nausea; Off Label Use;	Gabapentin			S	Oral	100 Milligram, Two Times A Day		Aurobindo
	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram, Every 1 Month		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Celebrex			S	Unknown	Occlusive Dressing Technique		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported
	Enbrel			S	Unknown	50 Milligram, Every Week		Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Dosage Form, Every Week		Not Reported

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Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbycusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Myochrysin	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Myochrysin	S	Intramuscular	50 Milligram, Every 3 Weeks	Not Reported
	Nortriptyline Hydrochloride	S	Oral	10 Milligram	Not Reported
	Apo-Gabapentin	S	Oral	100 Milligram, Two Times A Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every One Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 3 Weeks	Not Reported
	Orencia	S	Vaginal	750 Milligram, Every 1 Month	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Sulfasalazine	S	Oral	2.5 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Vitamin B1	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Omega-3	S	Unknown	Unk	Not Reported
	Omega-3	S	Unknown	1200 Milligram, Two Times A Day	Not Reported
	Fentanyl Matrix	S	Unknown	Unk	Not Reported
	Acetaminophen;Oxycodone Hydrochloride	C	Unknown	1 Dosage Form	Not Reported

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

Aclasta	C	Intravenous (not otherwise specified)	70 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750.0 Milligram, 1 Every 4 Weeks	Not Reported
Actonel	C	Unknown	36 Milligram, Every Week	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Once A Day	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Once A Day	Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Once A Day	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Once A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Two Times A Day	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	400 International Unit, Once A Day	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Once A Day	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Two Times A Day	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Once A Day	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Prednisone	C	Unknown	5 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	5 Gigabecquerel, Once A Day	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Once A Day	Not Reported
Tylenol	C	Oral	1000 Milligram, Once A	Not Reported

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			Day	
Vitamin B12	C	Unknown	Unk	Not Reported
Vitamin A	C	Unknown	Unk	Not Reported
Percocet	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Unknown	Unk	Not Reported
Lomotil	C	Unknown	Unk	Not Reported
Oxycocet	C	Unknown	Unk	Not Reported
Vitamin C	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Vitamin B6	C	Unknown	Unk	Not Reported
Vitamin E	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Two Times A Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200.0 Milligram, Two Times A Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram, Once A Day	Not Reported

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Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Every Week	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16205757	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020198		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure	Amlodipine Tablets			S	Oral	Unk, 1 Every 1 Day		Aurobindo
Fluctuation; Blood Pressure Increased;	Amlodipine Tablets			S	Oral	5 Milligram, Once A Day		Aurobindo
Colitis; Dental Caries; Diabetes Mellitus	Asacol			S	Unknown	800 Milligram, 3 Every 1 Day		Not Reported
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Asacol			S	Unknown	800 Milligram, 3 Every 2 Day		Not Reported
Gastrointestinal Disorder; Haematochezia;	Xeljanz			S	Unknown	Unk		Not Reported
Hypertension;	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
Musculoskeletal Stiffness; Pain In Extremity;	Diamicron			S	Unknown	Unk		Not Reported
Peripheral Swelling; Rheumatoid Arthritis;	Gliclazide			S	Unknown	Unk		Not Reported
Vitamin D Deficiency; Weight Increased	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Every Week		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Ebastine			C	Unknown	Unk		Not Reported
	Depo-Medrol			C	Intra-articular	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Milligram		Not Reported

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	Folic Acid	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk, 1 Every 1 Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16206143	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019772			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16347402	EXPEDITED (15-DAY)		OT	CA-SA-2019SA139156		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Condition	Sarilumab			S		20 Mg, Qow		Sanofi

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Aggravated; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Leflunomide	S	Oral		Sanofi
	Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
	Sulfasalazine	S			Not Reported
	Esomeprazole Magnesium Trihydrate	S			Not Reported
	Nicotinamide	S			Not Reported
	Thiamine Hydrochloride	S			Not Reported
	Esomeprazole Sodium	S			Not Reported
	Folic Acid	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Azathioprine	S			Not Reported
	Ciclosporin	S			Not Reported
	Enbrel	S			Not Reported
	Adalimumab	C			Not Reported
	Ergocalciferol	C			Not Reported
	Hydroxychloroquine	C			Not Reported
	Metformin	C			Not Reported
	Nexium [Esomeprazole Sodium]	C			Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Magnesium	C		Unk	Not Reported
	Gold	C			Not Reported
	Vitamin A [Retinol]	C			Not Reported
	Vitamin C [Ascorbic Acid]	C			Not Reported
	Dexpanthenol	C			Not Reported
	Esomeprazole Magnesium Trihydrate	C			Not Reported
	Nexium [Esomeprazole Magnesium]	C			Not Reported
	Riboflavin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16387694	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-029951		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Alendronic Acid	S	Unknown	70 Milligram, Every Week	Aurobindo
	Actemra	S	Unknown	360 Milligram, 1 Every 1 Month(S)	Not Reported
	Actemra	S	Unknown	680 Milligram, Once A Day, 1 Every 1 Month(S)	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week(S)	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Week(S)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Every Week	Not Reported
	Myochrysine	S	Intramuscular	50.0 Milligram, 1 Every 1 Month(S)	Not Reported
	Myochrysine	S			Not Reported
	Orencia	S	Unknown	780.0 Milligram, Every Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

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Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram, Two Times A Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Daily	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16387698	EXPEDITED (15-DAY)		DS, HO, OT	CA-AUROBINDO-AUR-APL-2019-029940		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased;	Alendronic Acid Tablets			S	Unknown	70 Milligram, Every Week		Aurobindo	
Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic	Alendronic Acid Tablets			S	Unknown	70 Milligram, 4 Every Week		Aurobindo	
	Actemra			S	Unknown	2.68 Milligram, Once Every 4 Weeks		Not Reported	
	Actemra			S	Unknown	360 Milligram, Once In A Month		Not Reported	
	Actemra			S	Unknown	360 Milligram, Every Week		Not Reported	
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Weeks		Not Reported	
	Apo-Ibuprofen			S	Oral	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Apremilast			S	Unknown	60 Milligram, Two Times A Day		Not Reported	
	Apremilast			S				Not Reported	
	Apremilast			S				Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Codeine			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	

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Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate	Enbrel	S	Unknown	25 Milligram, 2 Every 1 Week	Not Reported
Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis;	Enbrel	S	Unknown	25 Milligram, 1 Every 2 Week	Not Reported
Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapeutic Response	Humira	S	Subcutaneous	40 Milligram, 1 Every 2 Weeks	Not Reported
Decreased; Tongue Disorder; Ulcer	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Infliximab	S	Oral	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.0 Milligram, Once In A week	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Unknown	70.0 Milligram, Once In A week	Not Reported
	Methotrexate	S	Subcutaneous	10.0 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Oral	10.0 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Unknown	12.0 Milligram, Once In A Week	Not Reported
	Methotrexate	S	Unknown	10.0 Milligram, Once In A Week	Not Reported

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

Methotrexate	S	Unknown	12.5 Milligram, Once In A Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram, Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	10.0 Milligram, Once In A 2 Weeks	Not Reported
Methotrexate	S	Subcutaneous	15.0 Milligram, Once In A Week	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, 4 Every 1 Year	Not Reported
Methotrexate	S	Unknown	12 Milligram, 4 Every 1 Week	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, 4 Every 1 Week	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Once In A Month	Not Reported
Nitrazepam	S	Oral	5 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram, Once In A Week	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported

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

Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Ibuprofen	S	Oral	600 Milligram, Once A Day	Not Reported
Tocilizumab	S	Unknown	360.0 Milligram,	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16388032	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-030631		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Alendronic Acid Tablets			S	Oral	Unk		Aurobindo
Adverse Event; Alopecia;	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
Anti-Cyclic Citrullinated	Actemra			S	Unknown	Unk		Not Reported
Peptide Antibody Positive;	Actemra			S	Subcutaneous	Unk		Not Reported
Arthropathy; Condition	Arava			S	Oral	20 Milligram		Not Reported
Aggravated;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
Contraindicated Product								
Administered; Discomfort;								
Drug Ineffective; Drug								

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

Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram Once In A Week	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Golimumab	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	25 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine	S	Unknown	10 Milligram, Once A Day	Not Reported

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

Hydrochloride] Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Topicort	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Two Times A Day	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16440716	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028- 2822523-00		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported

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

Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16729866	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2896155-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16758967	EXPEDITED (15-DAY)		OT	PHHY2019CA200445			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abdominal Discomfort;	Lopresor	S	Unknown	Unk	Novartis
Abdominal Pain Upper;	Ciprofloxacin	S	Unknown	Unk	Not Reported
Arthralgia; Cardiac Failure	Clindamycin	S	Unknown	Unk	Not Reported
Congestive; Cough;	Codeine Phosphate	S	Unknown	Unk	Not Reported
Diarrhoea; Drug	Enalapril Maleate	S	Unknown	Unk	Not Reported
Hypersensitivity; Drug	Losartan Potassium	S	Unknown	Unk	Not Reported
Ineffective; Dyspnoea;	Methotrexate	S	Unknown	10 Mg, Qw	Not Reported
Gastric Disorder; Hepatic	Methotrexate	S	Subcutaneous	Unk, Qd	Not Reported
Steatosis; Hypertension;	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Malaise; Nausea; Rash	Isoniazid	S	Unknown	Unk	Not Reported
	Keflex	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Penicillin	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Biaxin	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cipro	C	Unknown	Unk	Not Reported
	Esomeprazole	C	Unknown	Unk	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Hydroxyquinoline Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16820448	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 3439		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Dorzolamide Hydrochloride And Timolol Maleate			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	16866723	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 3761			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17001941	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2989075-00		83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Dry Eye; Dry Mouth; Fatigue; Finger Deformity; Impaired Driving Ability; Macular Degeneration; Pain In Extremity; Rheumatoid Arthritis; Rheumatoid Nodule; Somnolence	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Levothyroxin			C				Not Reported
	Raloxifene			C				Not Reported
	Lidoderm			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17099946	EXPEDITED (15-DAY)		HO, OT	CA-COVIS PHARMA B.V.-2019COV00285		69 YR	Male	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Asthma; Atelectasis; Blood Disorder; Blood Immunoglobulin E Increased; Bronchial Wall Thickening; Bronchiolitis; Condition Aggravated; Cough; Dysphonia; Dyspnoea; Eosinophil Count Increased; Eosinophilic Granulomatosis With Polyangiitis; Fungal Infection; Infection Parasitic; Inflammation; Malaise; Oropharyngeal Pain; Pneumonia; Pneumonitis; Productive Cough; Secretion Discharge; Sinusitis; Skin Disorder; Sleep Disorder Due To A General Medical Condition; Spirometry Abnormal; Suprapubic Pain; Systemic Inflammatory Response Syndrome; Therapeutic Product Effect Incomplete; Underweight; Vasculitis; Weight Decreased; Wheezing	Alvesco			S	Respiratory (inhalation)	200 Mg, 1x/Day		Covis	
	Omnamis			S	Nasal	50 Mg, Unk		Covis	
	Pantoloc			S		40 Mg, Unk		Not Reported	
	Ivermectin			S		Unk		Not Reported	
	Plaquenil			S		Unk		Not Reported	
	Prednisone			S	Oral	5 Mg, Unk		Not Reported	
	Prednisone			S		50 Mg, Unk		Not Reported	
	Salbutamol Sulfate			S		100 Mg, Unk		Not Reported	
	Umeclidinium Bromide			S		62.5 Mg, Unk		Not Reported	
	Zenhale			S		Unk, 2x/Day		Not Reported	
	Sulfasalazine			C				Not Reported	
	Arava			C				Not Reported	
	<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>
18-Mar-2020	17440774	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX- 2018AP013701		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Arthropathy; C-Reactive	Minocycline			S	Unknown	Unk		Not Reported	

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

Protein Abnormal; C-Reactive Protein Increased;	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Hydroxychloroquine	S	Oral	Unk	Apotex
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Leflunomide	S			Apotex
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Unk	Not Reported
	Plaquenil /00072602/	S			Not Reported
	Plaquenil /00072602/	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S			Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Rituximab	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	Unk, Bid	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17523584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564553			Female	CAN

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

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

Atorvastatin	C	Unknown	Not Reported
Pantoprazole	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17526969	EXPEDITED (15-DAY)		HO	DE-CELLTRION INC.- 2020DE020115			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anaemia; Arthralgia; Fall; Lower Limb Fracture; Occult Blood Positive; Osteoarthritis; Pruritus; Urinary Tract Infection	Rituximab (Unknown)			S	Unknown	500 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Mabthera			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17543429	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2497274-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Fall; Fear Of Injection; Joint Swelling; Lower Limb Fracture; Malaise; Mammoplasty; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

Hydroxychloroquine Sulfate

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17553452	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201805-001630			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia;	Hydroxychloroquine Sulfate			S	Oral	Unk		Concordia
Dizziness; Drug	(Authorized Generic),Plaquenil							
Ineffective; Drug	Arava			S	Oral	Unk		Not Reported
Ineffective; Drug	Celecoxib			S	Unknown	Unk		Not Reported
Ineffective; Drug	Enbrel			S	Unknown	Unk		Not Reported
Ineffective; Drug	Methotrexate			S	Oral	25 Mg, Weekly		Not Reported
Ineffective; Drug	Humira			S	Subcutaneous	Unk		Not Reported
Ineffective; Fear Of	Prednisone			S	Oral	5 Mg, Qd		Not Reported
Injection; Joint Swelling;	Sulfasalazine			S	Unknown	Unk		Not Reported
Loss Of Personal	Domperidone			C				Not Reported
Independence In Daily								
Activities; Oedema								
Peripheral; Pain In								
Extremity; Rheumatoid								
Arthritis; Stress; Vomiting								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17553454	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201805-001673			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance;	Hydroxychloroquine			S	Unknown	Unk		Concordia
Headache; Loss Of	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
Personal Independence In	Enbrel			S	Unknown	Unk		Not Reported
Daily Activities;	Enbrel			S				Not Reported
Rheumatoid Arthritis;	Actemra			S	Unknown	Unk		Not Reported
Therapeutic Product Effect	Cimzia			S	Subcutaneous	Unk		Not Reported
Decreased; Treatment	Orencia			S	Unknown	Unk		Not Reported
Failure								

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

Orencia	S				Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Tofacitinib	S	Unknown	Unk		Not Reported
Leflunomide	C				Not Reported
Sulfasalazine	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17553635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567770			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205022		27 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous	Methotrexate			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported

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

		Hydroxychloroquine Sulfate		S	Unknown				Not Reported
		Ibuprofen		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554157	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1205088			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Impaired Work Ability; Pyoderma Gangrenosum; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554179	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205203			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypersensitivity; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr	
	Moxifloxacin Hydrochloride			S	Oral			Teva	
	Amoxicillin Trihydrate/Clavulanate			S	Unknown			Not Reported	
	Potassium Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554197	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204339			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Methotrexate			S	Subcutaneous			Barr	
	Adalimumab			S	Subcutaneous			Not Reported	

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

Apo-Leflunomide	S	Unknown	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram Daily; Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1204340			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Methotrexate			S	Unknown			Barr
Alopecia; Arthralgia;	Actemra			S	Unknown			Not Reported
Diarrhoea; Drug	Apo-Leflunomide			S	Unknown			Not Reported
Ineffective; Joint Stiffness;	Celebrex			S	Unknown			Not Reported
Liver Function Test	Enbrel			S	Unknown			Not Reported
Abnormal; Mobility	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Decreased; Pneumonia;	Orencia			S	Unknown			Not Reported
Swelling; Therapeutic	Rituximab			S	Intravenous drip			Not Reported
Product Effect Decreased;	Sulfasalazine			S	Unknown			Not Reported
Treatment Failure;	Bifidobacterium Bifidum			C				Not Reported
Vomiting								

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

Loperamide	C	Oral	Not Reported
Pantoprazole	C	Unknown	Not Reported
Xeljanz	C	Oral	10 Milligram Daily; Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554209	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020112925		33 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Enbrel			S	Unknown	50 Milligram		Pfizer	
	Enbrel			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Subcutaneous	25 Milligram		Pfizer	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported	
	Naproxen			S	Unknown	500 Milligram, Tid		Not Reported	
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported	
	Synthroid			C		Unk		Not Reported	
	Tramadol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554234	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205191		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	

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

Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554424	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1205198		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554449	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021302			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Naproxen			S	Unknown			Not Reported	
	Naproxen Sodium			S	Oral			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Xeljanz			S	Oral	5.0 Milligram 2 Every 1 Days		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554632	EXPEDITED (15-DAY)		OT	NVSC2020CA072976		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

C-Reactive Protein Increased;	Neoral	S	Subcutaneous	Unk	Novartis
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Treatment Failure	Cyclosporine	S	Unknown	Unk	Novartis
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Orencia	S	Subcutaneous	125 Mg	Not Reported
	Plaquenil	S	Oral	20 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3.0 Mg/Kg	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
	Enbrel	S	Subcutaneous	50 Mg 1 Every 1 Weeks	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565792		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Skin Reaction; Skin Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17554843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565710			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan Arava Enbrel Imuran [Azathioprine] Methotrexate Methotrexate Neoral Plaquenil [Hydroxychloroquine Sulfate] Sulfasalazine Citalopram Hydrobromide Citalopram Hydrobromide Prednisone	S S S S S S S S S C C C	Intravenous (not otherwise specified) Unknown Subcutaneous Subcutaneous Oral Oral Unknown Unknown Oral Unknown Unknown Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17555043	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565721		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan Cosentyx Enbrel Hydroxychloroquine Sulfate Leflunomide Methotrexate Orencia Simponi Sulfasalazine Naprosyn [Naproxen]			S S S S S S S S S S C		Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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18-Mar-2020	17555247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567695		70 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17555303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568898		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Alopecia; Anxiety; Asthenia; Depression; Drug Ineffective; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Malaise; Pain; Red Blood Cell Sedimentation Rate	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

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Increased; Synovitis			otherwise specified)	
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17555514	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1412		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Adverse Reaction;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Arthralgia; Contraindicated Product Administered;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Drug Ineffective; Dyspepsia; Fatigue;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Gastric Disorder; General Physical Health	Enbrel			S	Unknown			Not Reported
Deterioration; Insomnia;	Enbrel			S	Unknown			Not Reported
Joint Swelling; Malaise;	Etanercept			S	Unknown			Not Reported
Nausea; Pain; Rash;	Tofacitinib Citrate			S	Oral			Not Reported
Rheumatoid Arthritis; Sleep Disorder	Minocin			S	Unknown			Not Reported
	Minocycline Hcl			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

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Apo-Leflunomide	S	Unknown	Not Reported
Ustekinumab	S	Unknown	Not Reported
Ustekinumab	S	Subcutaneous	Not Reported
Tocilizumab	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Myochrysine	S	Parenteral	Not Reported
Myochrysine	S	Subcutaneous	Not Reported
Myochrysine	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Stelara	S	Unknown	Not Reported
Stelara	S	Subcutaneous	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apremilast	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Abatacept	C	Unknown	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17555803	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1027221		43 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Prednisone			S		25 Mg, Qd		Not Reported
	Prednisone			S		(7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S		15 Mg, Qd		Not Reported
	Prednisone			S		Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		(15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		Unk Unk, Qd		Not Reported
	Mycophenolate Mofetil			S		Unk Unk, Qd		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Mylan
	Methylprednisolone			C		Unk (Pulses)		Mylan
	Rituximab			C		Unk		Mylan
	Immunoglobulin I.V			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17555876	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020114584			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise;	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Methotrexate Sodium			S	Oral	Unk		Pfizer	

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Stomatitis; Weight Decreased	Sulfasalazine	S	Unknown	Unk	Pfizer
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17556462	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1027359			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Mylan	
	Abatacept			S	Unknown	Unk		Mylan	
	Roactemra			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557419	NON-EXPEDITED			NVSC2020US076875		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Novartis	
	Tacrolimus			S	Topical	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557715	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205280			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported	

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	Naproxen	C	Unknown		Not Reported
	Naproxen	C	Unknown	250 Milligram Daily;	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Hydrocortisone Valerate	C	Unknown		Not Reported
	Hydromorphone	C			Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Lyderm	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Sodium Aurothiomalate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557720	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205274		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bedridden; Crying; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205434			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling;	Methotrexate			S	Unknown			Barr

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Pain In Extremity; Peripheral Swelling	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557745	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205311		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression;	Methotrexate			S	Unknown			Barr	
Drug Hypersensitivity;	Arava			S	Unknown			Not Reported	
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported	
Intolerance; Headache;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Infection; Pharyngeal	Orencia			S	Intravenous (not			Not Reported	
Oedema; Rheumatoid					otherwise specified)				
Arthritis	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557806	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1205513			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Gait	Methotrexate			S	Subcutaneous			Barr	
Disturbance; Headache;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Influenza Like Illness;	Actemra			C				Not Reported	
Musculoskeletal Pain;	Actemra			C				Not Reported	
Musculoskeletal Stiffness;	Enbrel			C	Subcutaneous	50 Milligram Daily;		Not Reported	
Nausea; Osteoarthritis;	Humira			C	Subcutaneous			Not Reported	
Rheumatoid Arthritis;	Orencia			C	Intravenous (not			Not Reported	
Weight Fluctuation					otherwise specified)				
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	

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18-Mar-2020	17558048	NON-EXPEDITED		OT	NVSC2020US076308		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Diarrhoea; Gait Inability; Herpes Zoster; Rash; Skin Necrosis	Rituximab			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Novartis	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Cyclophosphamide			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17558470	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020114627		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Alopecia; Arthralgia; Bone Pain; Burning Sensation; Choking; Cough; Drug Ineffective; Drug Intolerance; Facial Pain; Fatigue; Fibromyalgia; Headache; Hot Flush; Hypoaesthesia; Immune System Disorder; Insomnia; Joint Range Of Motion Decreased; Melanocytic Naevus; Nasal Discomfort; Nausea; Night Sweats; Oropharyngeal Discomfort; Pain; Pain In	Enbrel			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Unknown	25 Mg, Unk		Pfizer	
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Day		Pfizer	
	Xeljanz			S	Oral	5 Mg, 1 Every 1 Day		Pfizer	
	Orencia			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Morphine			C	Unknown	Unk		Not Reported	
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported	

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Extremity; Pain In Jaw;
Peripheral Coldness;
Rhinoirrhoea; Skin Mass

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19-Mar-2020	12956625	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX- 2016AP014656		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Vomiting	Bisoprolol			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Apotex
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Norflox			S	Unknown	400 Mg, Unk		Apotex
	Apo-Bisoprolol			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Levofloxacin			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Erythromycin			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Apotex
	Arthrotec			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Mg, Qd		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Every Two Months		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
Humira			S	Subcutaneous	40 Mg, Unknown		Not Reported	
Meperidine Hcl			S	Unknown	Unk		Not Reported	

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Methotrexate	S	Oral	20 Mg, Q.Wk	Not Reported
Metronidazole	S	Unknown	5 Mg/MI, Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Flagyl /00012501/	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Erythromycin Estolate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	13516429	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-037987			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported

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

Methotrexate			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	13823542	EXPEDITED (15-DAY)	OT		CA-ORION CORPORATION ORION PHARMA-TREX2017- 2252		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Codeine			C	Unknown			Not Reported	
	Tylenol			C	Unknown			Not Reported	
	Lyrica			C	Oral			Not Reported	

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

Lyrica	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	13929206	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017- 2675		67 YR	Female	CAN

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

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

Simponi	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Imuran	C	Unknown	Not Reported
Arthrotec	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	14223269	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021499			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	640 Mg, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	14236211	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017- 3856			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Meloxicam			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Mobicox			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	14545702	EXPEDITED (15-DAY)		OT	CA-ROCHE-1715783		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper; Blood Pressure Diastolic Increased; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Increased; Blood Pressure Increased; Cough; Decreased Appetite; Epistaxis; Headache; Heart Rate	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015, Most Recent Dose On 06/Jun/2017 (683 Mg)		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Last Dose: 21/Sep/2015		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	

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

Increased; Influenza Like Illness; Infusion Related Reaction; Infusion Site Pain; Medication Error; Nausea; Pain; Platelet Count Decreased; Pruritus; Pyrexia; Sensation Of Foreign Body; Vomiting; Weight Increased; Weight Increased	Rituxan	S	otherwise specified)	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Acetaminophen	C	Oral		Not Reported
	Methotrexate	C			Not Reported
	Folic Acid	C			Not Reported
	Atovaquone	C			Not Reported
	Alendronate	C			Not Reported
	Vit D3	C			Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Diphenhydramine Hcl	C	Oral		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	14727278	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2018JPN056741		45 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cellulitis; Cytomegalovirus Infection; Neutrophil Count Decreased; Pancreatitis	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Two Weeks		Glaxosmithkline	
Acute; Pneumocystis Jirovecii Pneumonia;	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline	
White Blood Cell Count Decreased; White Blood Cell Count Decreased	Belimumab			S	Intravenous drip	10 Mg/Kg, Every Four Weeks		Glaxosmithkline	
	Belimumab			S	Intravenous drip	10 Mg/Kg		Glaxosmithkline	
	Belimumab			S	Intravenous drip	10 Mg/Kg, 1d		Glaxosmithkline	

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

Belimumab	S	Intravenous drip	10 Mg/Kg	Glaxosmithkline
Furosemide	S	Oral	Unk	Glaxosmithkline
Prednisolone	S	Oral	Unk	Glaxosmithkline
Prednisolone	S	Oral	70 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	50 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Intravenous drip	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	30 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	22.5 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	20 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	25 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	60 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	40 Mg, 1d	Glaxosmithkline
Prednisolone	S	Oral	35 Mg, 1d	Glaxosmithkline
Prograf	S	Oral	Unk	Not Reported
Cellcept	S	Oral	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Meropenem	S	Intravenous drip	1 G, Tid	Not Reported
Meropenem	S	Intravenous drip	Unk	Not Reported
Miraclid	S	Intravenous drip	300000 Iu, 1d	Not Reported
Omeprazole	S	Intravenous drip	40 Mg, 1d	Glaxosmithkline
Solu Medrol	C	Intravenous (not otherwise specified)	1000 Mg, 1d	Not Reported
Solu Medrol	C	Intravenous (not otherwise specified)	125 Mg, 1d	Not Reported

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

Valixa	C	Unk	Not Reported
Bonalon	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Baktar	C	1 Df, We	Not Reported
Baktar	C		Not Reported
Daikenchuto	C	Unk	Not Reported
Sodium Picosulfate Hydrate	C	Unk	Not Reported
Tenelia	C	Unk	Not Reported
Pitavastatin Calcium	C	Unk	Not Reported
Cardenalin	C	Unk	Not Reported
Rabeprazole Sodium	C	Unk	Not Reported
Azilva	C	Unk	Not Reported
Amlodipine Besilate	C	Unk	Not Reported
Azelnidipine	C	Unk	Not Reported
Carvedilol	C	Unk	Not Reported
Bayaspirin	C	Unk	Not Reported
Sennoside	C	Unk	Not Reported
Insulin Glargine (Genetical Recombination)	C	Unk	Not Reported
Spironolactone	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Persantin-L	C	Unk	Not Reported
Feburic	C	Unk	Not Reported
Bonviva	C	Unk	Not Reported
Novolin R	C	Unk	Not Reported
Trazenta	C	Unk	Not Reported
Polaprezinc	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	15207582	NON-EXPEDITED			US-PFIZER INC- 2018300600		63 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Methotrexate Sodium			S		Unk		Pfizer
	Cimzia			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Imuran			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	15605753	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018- 3227		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Sarilumab	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Prednisone	C	Unknown	Not Reported
Rabeprazole Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	15675159	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 2495		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Tolerance Decreased; Joint Swelling; Liver Function Test Increased; Platelet Count Decreased; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	

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

Actemra	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Coversyl	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Cephalexine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	15962909	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-013651		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Osteoarthritis; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200.0 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	10 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	200 Milligram, 2 Every 1 Day		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	16082171	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 06027		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis; Bursitis Infective; Crying; Infection; Inflammation; Leg Amputation; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Pneumonia; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Therapeutic Product Effect Incomplete	Infliximab			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Acidophilus			C	Unknown	Unknown		Not Reported
	Aspirin			C	Unknown	Unknown		Not Reported
	Calcium			C	Unknown	Unknown		Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	Unknown		Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown	Unknown		Not Reported
Lidocaine			C	Topical			Not Reported	
Metronidazole			C	Unknown	Unknown		Not Reported	
Nitroglycerin			C	Unknown	Unknkown		Not Reported	
Pantoloc			C	Unknown	Unknown		Not Reported	

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

Pregabalin	C	Unknown		Not Reported
Pregabalin	C			Not Reported
Pregabalin	C			Not Reported
Risedronate	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
Salbutamol	C	Unknown	Unknown	Not Reported
Salicylic Acid/Triamcinolone Acetonide	C	Intra-articular		Not Reported
Triamcinolone	C	Unknown		Not Reported
Tylenol	C	Unknown	Unknown	Not Reported
Xeljanz	C	Oral		Not Reported
Calcium Gluconate	C	Unknown	Unknown	Not Reported
Lactobacillus Acidophilus	C	Unknown	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Unknown	Not Reported
Salicylic Acid	C	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Suspension, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	16444894	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033815		28 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anovulatory Cycle;	Metformin			S	Unknown	Unk		Aurobindo
Bronchitis;	Metformin			S				Aurobindo
Dermatomyositis; Drug Ineffective; Gait Inability;	Cymbalta			S	Unknown	Unk		Not Reported
Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of Motion Decreased;	Plaquenil			S	Unknown	Unk		Not Reported
Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In	Prednisone			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Coumadin			S	Unknown	Unk		Not Reported

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

Unapproved Indication;	Methotrexate	C	Unknown	Unk	Not Reported
Thrombosis; Uterine	Xarelto	C	Unknown	Unk	Not Reported
Disorder; Weight	Imuran	C	Unknown	Unk	Not Reported
Increased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	16866958	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-092201		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Abatacept			S	Unknown			Bristol Myers Squibb	
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown	50 Milligram		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sarilumab			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported	
	Kevzara			S	Unknown	Unk		Not Reported	
	Mefenamic Acid			S	Unknown			Not Reported	
	Metformin			C	Unknown			Not Reported	
	Synthroid			C	Unknown			Not Reported	

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

Folic Acid	C	Unknown		Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17124253	EXPEDITED (15-DAY)	HO, OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-113880			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk (12.5 Milligram, 4 Every 1 Week)		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, Qd		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)			S	Unknown	Unk		Not Reported
	Human Immunoglobulin (Immunoglobulin Human Normal)			S	Intravenous (not otherwise specified)	70 Gram		Not Reported
	Infliximab			S	Unknown	5 Milligram		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported

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

	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Oral	10 Milligram, Qd (5 Milligram, 2 Every 1 Day)	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17390832	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0682		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tylenol			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17397400	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA032774			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Contraindicated Product	Cosentyx	S	Unknown	Unk	Novartis
Administered; Drug	Leflunomide	S	Unknown	Unk	Not Reported
Ineffective; Drug-Induced	Methotrexate	S	Unknown	Unk	Not Reported
Liver Injury	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17450142	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 1058		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Methotrexate (Trade Name			S	Oral			Not Reported
Alopecia; Contraindicated	Unknown)							
Product Administered;	Methotrexate (Trade Name			S	Subcutaneous			Not Reported
Discomfort; Drug	Unknown)							
Hypersensitivity; Drug	Methotrexate (Trade Name			S	Unknown			Not Reported
Intolerance; Duodenal	Unknown)							
Ulcer Perforation; Fatigue;	Methotrexate (Trade Name			S	Unknown			Not Reported
Glossodynia; Hand	Unknown)							
Deformity; Helicobacter	Enbrel			S	Unknown			Not Reported
Infection; Hepatic Enzyme	Enbrel			S	Unknown			Not Reported
Increased; Maternal	Plaquenil			S	Unknown			Not Reported
Exposure During	Plaquenil			S	Oral			Not Reported
Pregnancy; Pain;	Arava			S	Unknown			Not Reported
Pemphigus; Pericarditis;	Arava			S	Oral			Not Reported
Product Use Issue; Rash;	Cimzia			S	Unknown			Not Reported
Rheumatoid Arthritis;	Cimzia			S	Subcutaneous			Not Reported
Swelling; Synovitis;	Orencia			S	Unknown			Not Reported
Systemic Lupus								
Erythematous; Therapy								
Non-Responder;								
Treatment Failure; Wound								

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

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Actemra	S	Unknown	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Atasol [Paracetamol]	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine;Hydrochloride;Pseudo ephedrine	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Desoximetasone	S	Oral	Not Reported
Diclofenac	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Topicort	S	Subcutaneous	Not Reported

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

	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Vitamin C	C	Unknown		Not Reported
	Vitamin D	C	Unknown		Not Reported
	Alaskan Salmon Oil	C	Unknown		Not Reported
	Glucosamine	C	Unknown		Not Reported
	Lansoprazole	C	Unknown		Not Reported
	Ativan	C	Unknown	As Needed	Not Reported
	Salazopyrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17557868	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013437		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Celecoxib Capsules			S	Unknown	Unk		Aurobindo
	Celecoxib Capsules			S				Aurobindo
	Anakinra			S	Unknown	100 Milligram		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Once A Day		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
	Apo-Prednisone			S	Unknown	7 Milligram, Once A Day		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	200 Milligram		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	25 Milligram		Not Reported

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

Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	1 Milliliter, Every Week	Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, 1 Every 1 Month	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Once A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, 1 Every 1 Month	Not Reported
Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
Altace	C	Unknown	5 Milligram	Not Reported
Altace	C	Unknown	10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C	Unknown	300 Milligram	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once A Day	Not Reported
Atorvastatin Calcium	C	Unknown	40 Milligram, Once A Day	Not Reported
Citalopram Hydrobromide	C	Unknown	20 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	0.625 Milligram	Not Reported
Conjugated Estrogens	C	Unknown	20 Milligram	Not Reported
Cymbalta	C	Unknown	30 Milligram, Four Times/Day	Not Reported
Cymbalta	C	Unknown	60 Milligram	Not Reported
Cymbalta	C	Unknown	120 Milligram, Once A Day	Not Reported
Cipralex	C	Unknown	20 Milligram	Not Reported

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

Escitalopram	C	Unknown	10 Milligram	Not Reported
Estrace	C	Unknown	0.5 Milligram	Not Reported
Gabapentin	C	Oral	100 Milligram	Not Reported
Gabapentin	C	Unknown	3000 Milligram	Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram	Not Reported
Hydromorphone Hydrochloride	C	Oral	3 Milligram, Two Times A Day	Not Reported
Hydromorphone Hydrochloride	C	Oral	30 Milligram, Two Times A Day	Not Reported
Mupirocin	C	Topical	Unk	Not Reported
Pantoloc	C	Intravenous (not otherwise specified)	20 Milligram, Once A Day	Not Reported
Shark Liver Oil	C	Unknown	Unk	Not Reported
Tapentadol Hydrochloride	C	Unknown	50 Milligram	Not Reported
Taro-Mupirocin	C	Topical	Unk	Not Reported
Tramacet	C	Oral	Unk	Not Reported
Tramadol Hydrochloride	C	Oral	50 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17557974	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201805-001639			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non-Responder	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17558021	EXPEDITED (15-DAY)		HO, OT	CA-ADVANSZ PHARMA-GSH201711-006521			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Asthenia; Condition Aggravated; Diarrhoea; Dizziness; Fatigue; Hernia; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia
	Apo-Folic			S	Unknown	1 Dosage Form, Biw(Twice A Week)		Not Reported
	Apo-Gabapentin			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Esomeprazole Magnesium Trihydrate			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, 4 Times In A Week		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17558061	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-013432		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10.0 Milligram		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400.0 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported

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

Arthritis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Once A Day	Not Reported
	Methotrexate	S	Oral	25.0 Milligram	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Every Week	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400.0 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000.0 Milligram, Two Times A Day	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Salazopyrin	C	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50.0 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17558697	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021515			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17558984	EXPEDITED (15-DAY)		OT	JP-ADVANS PHARMA- GSH201806-002196			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pyrexia; Rash Maculo- Papular; Toxic Skin Eruption; Vitreous Detachment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	100 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Film-Coated Tablet)		Concordia

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

Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg, Qod (Film-Coated Tablet)	Concordia
Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	400 Mg, Qod (Film-Coated Tablet)	Concordia
Onetram	C		Unk	Not Reported
Nexium	C		Unk	Not Reported
Prerenal	C		Unk	Not Reported
Seroquel	C		Unk	Not Reported
Magnesium Oxide	C		Unk	Not Reported
Cefalexin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559013	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 08978		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Rheumatoid Arthritis; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported

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

	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Imuran	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559017	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-08970		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Etanercept			S	Unknown	Unknown		Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Parenteral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported

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

Methotrexate	S	Parenteral	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Arava	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Tofacitinib	C	Unknown	Unknown	Not Reported
Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569481		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

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

Simponi	S	Subcutaneous	Not Reported
Lyrica	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559216	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021540		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Dependence; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559217	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568742			Female	CAN

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

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

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559478	EXPEDITED (15-DAY)		OT	CA-ROCHE-2565794		52 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559517	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568861		89 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported

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

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Naprosyn [Naproxen]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Vioxx	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559606	EXPEDITED (15-DAY)		HO, OT	US-APPCO PHARMA LLC-2081773		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma	
	Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559853	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021632		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown	20 Milligram, Qd		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported	
	Humira			S	Subcutaneous	20 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported	
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported	
	Prednisone			S	Oral	5 Milligram, Qd		Not Reported	

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Sulfasalazine

S

Unknown

1000 Milligram, Bid

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559938	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1439		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Methotrexate (Trade Name			S	Unknown			Not Reported
Abdominal Pain Upper;	Unknown)			S	Unknown			Not Reported
Alopecia; Arthralgia; Bone	Enbrel			S	Unknown			Not Reported
Pain; Burning Sensation;	Xeljanz			S	Oral			Not Reported
Choking; Cough; Drug	Xeljanz			S	Oral			Not Reported
Ineffective; Drug	Orencia			S	Unknown			Not Reported
Intolerance; Facial Pain;	Actemra			S	Unknown			Not Reported
Fatigue; Fibromyalgia;	Humira			S	Subcutaneous			Not Reported
Headache; Hot Flush;	Hydroxychloroquine			S	Unknown			Not Reported
Hypoaesthesia; Immune	Tylenol			C	Unknown			Not Reported
System Disorder;	Morphine			C	Unknown			Not Reported
Insomnia; Joint Range Of								
Motion Decreased;								
Melanocytic Naevus;								
Nasal Discomfort; Nausea;								
Night Sweats;								
Oropharyngeal								
Discomfort; Pain; Pain In								
Extremity; Pain In Jaw;								
Peripheral Coldness;								
Rhinorrhoea; Skin Mass								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559980	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021788		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein	Orencia			S	Unknown			Bristol Myers Squibb
Abnormal; Drug	Actemra			S	Intravenous (not			Not Reported
Ineffective; Rheumatoid					otherwise specified)			
Arthritis; Therapeutic								

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

Product Effect Incomplete	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	C	Unknown	500 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566109			Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17559994	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021821			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560048	EXPEDITED (15-DAY)		OT	GB-ACCORD-176336		29 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin/Atorvastatin			S	Unknown	Unk		Not Reported	
	Calcium								
	Clopidogrel			S	Unknown	Unk		Not Reported	
	Apixaban			S	Unknown			Not Reported	
	Warfarin			S	Unknown	Unk		Not Reported	
	Rivaroxaban			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560201	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021912			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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

Methotrexate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560261	EXPEDITED (15-DAY)		OT	JP-ADVANSZ PHARMA-202003001629			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glossodynia; Hangnail; Nail Avulsion; Onychoclasia; Sjogren'S Syndrome; Stomatitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk, Resumption		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560263	EXPEDITED (15-DAY)		HO, OT	FR-ADVANSZ PHARMA-202003001668			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Hypersensitivity	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg		Concordia	
	Nivaquine			C		100 Mg		Not Reported	
	Nivaquine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560475	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021879			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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Personal Independence In Daily Activities;	Humira	S	Subcutaneous		Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine Sulphate	S	Oral		Not Reported
Nail Disorder;	Methotrexate	S	Oral		Not Reported
Onychomycosis	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021576		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17560673	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021952		69 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Carotid Arteriosclerosis; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Off Label Use; Osteoarthritis; Rectal Haemorrhage; Rheumatoid Arthritis; Thyroid Cancer	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Intra-arterial			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral	2.5 Milligram, Qd		Not Reported	
	Enbrel			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561009	EXPEDITED (15-DAY)		HO	CA-PFIZER INC- 2020118255			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Drug Ineffective	Methotrexate Sodium			S	Unknown			Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561066	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118198			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer	
	Atorvastatin Calcium			S		Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported	
	Simponi			S	Subcutaneous	50 Mg, Monthly		Not Reported	
	Alprazolam			C		1 Mg, Unk		Not Reported	
	Folic Acid			C		5 Mg, Unk		Not Reported	
	Naprosyn [Naproxen]			C		500 Mg, 2x/Day		Not Reported	
	Pantoloc [Pantoprazole]			C		Unk		Not Reported	
	Prednisone			C		5 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561096	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA202009727			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)			Shire	
	Azathioprine			S	Unknown			Not Reported	
	Cyclophosphamide			S	Unknown			Not Reported	
	Tofacitinib Citrate			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561109	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008889			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Intolerance; Leukopenia	Hydroxychloroquine	S	Oral	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Etanercept	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561204	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021856		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb	
	Acetaminophen			S	Unknown	325 Milligram		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Acetaminophen			S	Unknown			Not Reported	
	Arava			S	Oral	20 Milligram, Qd		Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown	50 Milligram		Not Reported	
	Enbrel			S	Unknown	50 Milligram, 4 Every One Week		Not Reported	
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Q12h		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Subcutaneous	2000 Milligram		Not Reported	
	Leflunomide			S	Unknown	200 Milligram, Qd		Not Reported	

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Tylenol	S	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Unk, Qwk
Synthroid	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561711	EXPEDITED (15-DAY)		HO	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022131			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	1.5 Gram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561810	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA- 1206362		61 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Influenza; Injection Site Pain; Pain; Pain In Extremity; Rheumatoid	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported

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

Arthritis; Skin Burning Sensation; Skin Exfoliation	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Hydromorph Contin	C		Not Reported
	Prednisone	C		Not Reported
	Allopurinol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561811	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1206466			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Alopecia	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C				Not Reported
	Leflunomide			C				Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561822	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206400		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Sounds Abnormal; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported

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

Methotrexate	S	Oral	Not Reported
Methotrexate	S		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported
Alprazolam	C	Unknown	Not Reported
Amlodipine	C	Unknown 5 Milligram Daily;	Not Reported
Asa	C	Unknown	Not Reported
Bisoprolol Fumarate	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Paroxetine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported
Simvastatin	C	Unknown	Not Reported
Telmisartan	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561842	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206475			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Lung Disorder; Platelet Count Decreased; Rheumatoid Arthritis; Septic Shock; Synovitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported	
	Tofacitinib			S	Unknown	10 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561854	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206317		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561863	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206324		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Methotrexate			S	Unknown			Barr	
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported	
	Orencia			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561870	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206272		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthralgia; Condition Aggravated; Dry Eye; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Headache; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Thirst; Tremor; Upper Respiratory Tract Infection	Methotrexate			S	Unknown			Barr	
	Arava			S	Oral	10 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Apo-Naproxen			C		1000 Milligram Daily;		Not Reported	
	Apo-Prednisone			C				Not Reported	
	Desoximetasone			C				Not Reported	
	Ergocalciferol			C	Oral			Not Reported	
	Folic Acid			C		1 Milligram Daily;		Not Reported	
	Leucovorin Calcium			C				Not Reported	
	Pantoprazole Magnesium			C		40 Milligram Daily;		Not Reported	
	Pantoprazole Magnesium			C		1 Dosage Forms Daily;		Not Reported	
	Vitamin C [Ascorbic Acid]			C	Oral			Not Reported	
	Wellbutrin			C		300 Milligram Daily;		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17561877	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206389			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Loss Of Personal Independence In Daily Activities; Treatment Failure	Methotrexate			S	Unknown			Barr	
	Enbrel			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Tofacitinib			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562040	NON-EXPEDITED			US-PFIZER INC-2020117515		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Ciprofloxacin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562437	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022525			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness;	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	

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Liver Function Test	Enbrel	S	Unknown		Not Reported
Abnormal; Mobility	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Decreased; Pneumonia;	Leflunomide	S	Unknown		Not Reported
Swelling; Therapeutic	Methotrexate	S	Unknown		Not Reported
Product Effect Decreased;	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Treatment Failure;					
Vomiting	Sulfasalazine	S	Unknown		Not Reported
	Bifidobacterium Bifidum	C	Unknown		Not Reported
	Loperamide	C	Oral		Not Reported
	Pantoprazole	C	Unknown	Unk, Tid	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562446	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020116277		60 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Visual Acuity Reduced	Dobupal			S		Unk Unk, 1x/Day (1/24)		Pfizer
	Hydrochlorothiazide/Losartan			S		50 Mg/12.5 Mg		Not Reported
	Potassium							
	Eutirox			S		Unk Unk, 1x/Day (1/24)		Not Reported
	Dolquine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567649			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug-Induced Liver Injury; Dyspepsia	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	300-400 ; Ongoing		Not Reported
	Leflunomide			S	Unknown			Not Reported

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

	Sulfasalazine		S	Unknown	Ongoing			Not Reported	
	Simponi		S	Unknown	Ongoing			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1206591		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Methotrexate			S	Unknown			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Asa			C	Unknown			Not Reported	
	Bisoprolol			C	Unknown			Not Reported	
	Candesartan			C	Unknown			Not Reported	
	Pantoprazole Magnesium			C	Unknown			Not Reported	
Rosuvastatin Calcium			C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562971	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022558		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	

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Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17563672	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022540			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17563850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021523		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported

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

Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Somnolence; Visual Impairment	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	12928888	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091881			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8.0 Millilitre Per Kilogram		Not Reported	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Anakinra			S	Subcutaneous	Unk		Not Reported	
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported	
	Anakinra			S	Oral	Unk		Not Reported	
	Apo-Leflunomide			S	Oral	20 Milligram, Qh		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported	
	Apo-Leflunomide			S	Oral	20 Milligram, Qcycle		Not Reported	

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

Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Arava	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qh	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Qcycle	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Actonel	S	Oral	35 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	300 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qwk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qh	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qcycle	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Form, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported

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Risedronate Sodium	S	Unknown	35 Milligram, One Every One Week	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	10 Milligram, Qd	Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Risedronic Acid	S	Unknown	35 Milligram, Qwk	Not Reported
Hydroxychloroquine	C	Unknown	300 Milligram, Qd	Not Reported
Risedronate	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	13519848	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-000478		56 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung Disease; Joint Swelling; Off Label Use; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	10 Mg, Unk		Not Reported
	Minocycline Hcl			S	Unknown	Unk		Not Reported
	Marijuana			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Cannabis Sativa			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Oxycodone Hydrochloride			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported

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

Hydroxychloroquine Sulphate	S	Unknown	400 Gram	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Prednisone	C	Unknown	Unk, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Q2wk	Not Reported
Actemra	C	Unknown		Not Reported
Cannabis Sativa	C	Unknown		Not Reported
Enbrel	C	Unknown		Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Sulfasalazine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	13594604	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941652		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	13901217	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170125543		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Simponi	S	Subcutaneous	Not Reported
Contraindicated Product Administered; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hepatotoxicity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pain; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Simponi	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Kineret	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported
	Apo-Hydroxyquine	S	Subcutaneous	Not Reported

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

Actonel	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate	S	Unknown	Not Reported
Risedronate Sodium	S	Other	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Adalimumab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	14326215	NON-EXPEDITED			US-AMGEN- USASP2017190208		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen
	Asa			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Macrobid [Nitrofurantoin]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	15385213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184735		61 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	15565611	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-CELLTRION INC.- 2018CA023567			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

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

Grip Strength Decreased;	Methotrexate Sodium	S	Oral	Unk	Not Reported
Headache; Injection Site	Methotrexate Sodium	S	Oral	Unk	Not Reported
Reaction; Joint Swelling;	Sulfasalazine	S	Unknown	500 Milligram, Unk	Not Reported
Loss Of Personal	Sulfasalazine	S	Unknown	Unk	Not Reported
Independence In Daily	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Activities; Musculoskeletal	Xeljanz	S	Unknown	5 Mg, Unk	Not Reported
Stiffness; Nail Disorder;	Actemra	S	Unknown	Unk	Not Reported
Onychomadesis;	Humira	S	Subcutaneous	Unk	Not Reported
Onychomycosis	Cimzia	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Arava	C	Oral	Unk	Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	15620814	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556952-00		43 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Actonel			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	15625325	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557482-00		46 YR	Female	CAN

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

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Independence In Daily Activities; Malaise;	Hydroxychloroquine	S	Unknown	Not Reported
Musculoskeletal Stiffness; Pain; Pain In Extremity;	Leflunomide	S	Unknown	Not Reported
Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	15629661	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557290-00		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris;	Humira			S	Subcutaneous			Not Reported	
Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not			Not Reported	

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

		otherwise specified)	
Asa	C		Not Reported
Clonazepam	C	Oral	Not Reported
Desipramine	C	Unknown	Not Reported
Nitroglycerin	C		Not Reported
Rosuvastatin Calcium	C	Oral	Not Reported
Gabapentin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	15635193	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-105819			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral			Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	25 Mg, Qwk		Not Reported
	Prednisone			C	Unknown	30 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16075459	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-012877		58 YR	Female	CAN

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Alendronic Acid Tablets			S	Unknown	70 Milligram, 1 Every Week		Aurobindo
	Actemra			S	Unknown	680 Milligram, 1 Every 4 Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every Week		Not Reported
	Actemra			S	Unknown	360 Milligram, 1 Every Month		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 1 Every 2 Weeks		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Every Week		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram		Not Reported
	Methotrexate			S	Unknown	12 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every Month		Not Reported
	Orencia			S	Unknown	780 Milligram, Every Week		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, Two Times A Day		Not Reported

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Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16122724	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-026025			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Apo-Prednisone			S	Oral	20 Nanogram		Not Reported

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Meloxicam	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Methotrexate	C	Unknown	25 Milligram, Qwk	Not Reported
Methotrexate	C	Unknown	Unk, Q4wk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Acetaminophen & Cod. Phosp.	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16145460	EXPEDITED (15-DAY)		HO, OT	CA-CELLTRION INC.- 2019CA019978			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly, Unknown		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q2wk (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	25 Mg, 2x/Week (End Date: 2011)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk (1 Every 2 Week)		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Etanercept			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
	Etanercept			S	Unknown	50 Mg, Weekly		Not Reported
	Celebrex			S		Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	12 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15.5, Weekly		Not Reported

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

Product Use Issue; Rash;	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported
Rash Pruritic; Red Blood	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
Cell Sedimentation Rate	Methotrexate Sodium	S	Unknown	10 Mg, Unk	Not Reported
Increased; Rheumatoid	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
Arthritis; Rheumatoid	Methotrexate Sodium	S	Unknown	15mg, Weekly	Not Reported
Nodule; Skin Necrosis;	Methotrexate Sodium	S	Unknown	17.5 Mg, Weekly	Not Reported
Skin Ulcer; Therapeutic	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
Product Effect Decreased;	Methotrexate Sodium	S	Unknown	12.5 Mg, Weekly	Not Reported
Therapeutic Product Effect	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
Incomplete; Therapeutic	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
Response Decreased;	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
Ulcer	Methotrexate Sodium	S	Unknown	12 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Oral	12.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Mg, Weekly	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q4wk	Not Reported
	Methotrexate Sodium	S	Unknown	15 Mg, Q4wk	Not Reported

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

Methotrexate Sodium	S	Unknown	15.5 Mg, Weekly	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q4wk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12 Mg, Weekly	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Mg, Monthly	Not Reported
Simponi	S	Unknown	360 Mg, Monthly	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Mg, Unk	Not Reported
Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Leflunomide	S		20 Mg, Daily	Not Reported
Leflunomide	S		20 Mg, 5 Days Out Of 7	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	20 Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 1x/Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Daily	Not Reported

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

Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, 2x/Day	Not Reported
Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, (Every 4 Weeks)	Not Reported
Actemra	S	Unknown	2.68 Mg, Q4wk,	Not Reported
Actemra	S	Unknown	360 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Qmo	Not Reported
Actemra	S	Unknown	680 Mg, Monthly	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	760 Mg, Weekly	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Weekly	Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Cyclic (Once Every Two Weeks)	Not Reported
Myochrysine	S	Unknown	50 Mg, Monthly	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported

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

Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Week	Not Reported
Hydroxychloroquine	S	Oral	20 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	200 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly	Not Reported
Rituximab	S	Unknown	1000 Mg, 2x/Day	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Q2wk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	70 Mg, Weekly	Not Reported
Prednisone	C	Unknown	10 Mg, 1x/Day	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, (Every 2 Hours)	Not Reported
Prednisone	C		10 Mg, Unk	Not Reported
Cyclosporin	C	Unknown	150 Mg, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisolone	C		Unk	Not Reported
Alendronate	C	Unknown	Unk	Not Reported
Alendronate	C	Unknown	70 Mg, Weekly	Not Reported
Alendronate	C	Unknown	70 Mg, Weekly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16211394	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-020276		67 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Meloxicam			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	160 Milligram, Every Week		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Depo Medrol			C	Intra-articular	80 Milligram		Not Reported
	Depo Medrol			C	Intramuscular	80 Milligram, Once A Day		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			C	Oral	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16216662	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-020655		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo
	Risedronate			S	Unknown	16.35 Milligram, 1 Every 2 Weeks		Aurobindo
	Risedronate Tablet			S	Oral	35 Milligram, 1 Every 1 Week		Aurobindo
	Actemra			S	Subcutaneous	Unk		Not Reported

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

Intolerance; Hypertension; Ill-Defined Disorder;	Actonel	S	Unknown	35 Milligram, 1 Every 1 Week	Not Reported
Infection; Intentional Product Use Issue; Loss Of Consciousness;	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
Mobility Decreased;	Anakinra	S	Subcutaneous	100 Milligram	Not Reported
Nausea; Nodule; Off Label Use; Pulmonary Fibrosis;	Anakinra	S	Subcutaneous	Unk	Not Reported
Red Blood Cell Sedimentation Rate	Apo-Leflunomide	S	Unknown	20 Milligram, Cyclical	Not Reported
Abnormal; Rheumatoid Arthritis; Rheumatoid	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
Factor Positive; Synovitis	Apo-Leflunomide	S	Oral	20 Milligram, One Every One Hour	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Unknown	40 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram, 1 Every Two Weeks	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram, One Every One Hour	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Two Times A Day	Not Reported
	Hydroxychloroquine	S	Unknown	Unk, 1 Every 1 Week	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

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

	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
	Plaquenil	S	Unknown	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Two Times A Day	Not Reported
	Risedronate	C	Unknown	35 Milligram, Every Week	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16227903	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.- 2019CA020634			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthralgia;	Infliximab Pfizer (Unknown)			S	Unknown	Unk		Not Reported
Bronchitis; C-Reactive	Enbrel			S	Unknown	50 Milligram		Not Reported
Protein Increased; Colitis	Enbrel			S	Unknown	Unk		Not Reported
Microscopic;								
Contraindicated Product	Methotrexate Sodium			S	Unknown	Unk		Not Reported
Administered;	Methotrexate Sodium			S	Unknown	25 Milligram, Qd		Not Reported
Diverticulitis; Drug	Sulfasalazine			S	Unknown	Unk		Not Reported
Hypersensitivity; Drug	Celebrex			S		Unk		Not Reported
Ineffective; Drug	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
Intolerance; Glaucoma;	Cimzia			S	Subcutaneous	Unk		Not Reported
Hepatic Enzyme	Cimzia			S	Unknown	Unk		Not Reported
Increased;	Orencia			S	Unknown	Unk		Not Reported
Hypersensitivity;	Actemra			S	Unknown	1 Dose		Not Reported
Hypertension; Limb	Arava			S	Unknown	Unk		Not Reported
Discomfort; Pneumonia;								
Skin Reaction; Synovitis;								
Thyroid Disorder;								
Thyroxine Decreased;								

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

Treatment Failure; Vomiting	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Desoximetasone	S		Unk	Not Reported
	Humira	S		Unk	Not Reported
	Methadone	S		Unk	Not Reported
	Rampril	S		Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Estrogel	C	Unknown	0.6 %, Three Times A Day	Not Reported
	Estrogel	C	Unknown	1.0 Df Qd	Not Reported
	Estradiol	C		Unk, Tid	Not Reported
	Calcium	C		500 Milligram, Qd	Not Reported
	Xalatan	C	Ophthalmic	50 Microgram, Qd (50 Mcg 0.005% 1 Drop)	Not Reported
	Cosopt	C		Unk, 2x/Day	Not Reported
	Furosemide	C	Unknown	40 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Vitamin D	C		10000 Unit, Weekly	Not Reported
	Jamp K20	C		1500 Mg, 1x/Day	Not Reported
	Zingiber Officinale	C	Oral	500 Mg, As Needed	Not Reported
	Dorzolamide Hcl And Timolol Maleate	C	Unknown	Unk, 2x/Day	Not Reported
	Ergocalciferol	C	Unknown	Unk, Weekly	Not Reported
	Ergocalciferol	C	Unknown	Unk, Qd	Not Reported
	Morphine	C	Unknown	Unk Unk, As Necessary	Not Reported

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

Potassium Chloride	C	Unknown	1500 Mg, 1x/Day (Qd)	Not Reported
Gravol Ginger	C	Oral	500 Milligram, As Needed	Not Reported
Baclofen	C	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16446297	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2822466-00		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Humira			S	Subcutaneous			Not Reported	
Contraindicated Product	Apo-Prednisone			S	Unknown			Not Reported	
Administered; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Ineffective; Feeling	Orencia			S	Unknown			Not Reported	
Abnormal; Insomnia; Pain	Actemra			S	Unknown			Not Reported	
In Extremity; Peripheral	Arava			S	Unknown			Not Reported	
Swelling; Pneumonia;	Methotrexate			S	Unknown			Not Reported	
Rheumatoid Factor	Xeljanz			C	Oral			Not Reported	
Increased; Rheumatoid	Plaquenil			C				Not Reported	
Nodule; Somnolence;									
Weight Increased									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16510049	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570129-00		49 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chest	Humira			S	Subcutaneous			Not Reported	
Pain; Drug Ineffective;	Actemra			S	Unknown			Not Reported	
Pain; Spinal Compression	Arava			S	Oral			Not Reported	
Fracture; Treatment	Enbrel			S	Unknown			Not Reported	
Failure	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	

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

Xeljanz

S

Oral

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16682901	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 22253		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance; Liver Function Test Increased; Off Label Use; Palpitations; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Acetaminophen And Codeine			C	Unknown			Not Reported
	Acetaminophen And Codeine			C	Unknown	Unknown		Not Reported
Acetaminophen And Codeine			C	Unknown	Unknown		Not Reported	
Amitriptyline Hydrochloride			C	Unknown	Unknown		Not Reported	
Aspirin			C	Unknown	Unknown		Not Reported	

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

Baclofen	C	Unknown	Unknown	Not Reported
Betahistine Hydrochloride	C	Unknown	Unknown	Not Reported
Caffeine	C	Unknown	Unknown	Not Reported
Calcium	C	Unknown	Unknown	Not Reported
Clonidine	C	Unknown	Unknown	Not Reported
Clonidine Hydrochloride	C	Unknown	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Unknown	Not Reported
Fluticasone Propionate	C	Unknown	Unknown	Not Reported
Folinic Acid	C	Unknown	Unknown	Not Reported
Gabapentin	C	Unknown	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Unknown	Not Reported
Losartan	C	Unknown	Unknown	Not Reported
Metoprolol Tartrate	C	Unknown	Unknown	Not Reported
Mometasone Furoate	C	Unknown	Unknown	Not Reported
Naproxen	C	Unknown	Unknown	Not Reported
Naproxen	C	Unknown	Unknown	Not Reported
Tylenol With Codeine	C	Unknown	Unknown	Not Reported
Folic Acid	C	Unknown		Not Reported
Plaquenil	C	Unknown		Not Reported
Acetaminophen	C	Unknown	Unknown	Not Reported
Codeine	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16700535	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2885154-00		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Humira			S	Subcutaneous			Not Reported
Arthritis; Arthropathy;	Adalimumab			S	Subcutaneous			Not Reported
Body Height Below Normal; Bone Density	Adalimumab			S				Not Reported

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

Decreased; C-Reactive Protein Increased;	Enbrel	S	Subcutaneous	Not Reported
Condition Aggravated;	Enbrel	S		Not Reported
Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present;	Triamcinolone Acetonide	S	Intra-articular	Route: Suspension Intra-Articular Not Reported
Gastroenteritis Viral;	Triamcinolone Acetonide	S		Not Reported
Human Antichimeric Antibody Positive;	Apo-Prednisone	S	Oral	Not Reported
Hypocalcaemia;	Apo-Prednisone	S		Not Reported
Hypokalaemia;	Apo-Naproxen	S	Unknown	Not Reported
Hypotension;	Apo-Naproxen	S		Not Reported
Immunodeficiency;	Methotrexate	S	Subcutaneous	Not Reported
Impaired Quality Of Life;	Methotrexate	S		Not Reported
Joint Destruction; Joint Effusion; Joint Injury;	Naproxen	S	Unknown	Not Reported
Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Obesity; Off Label Use; Pleural Effusion; Polyarthritis;	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
Prescribed Underdose;	Tocilizumab	S		Not Reported
Psoriasis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Wheelchair User	Orencia	S		Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S		Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S		Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported
	Immune Globulin (Human)	S	Intravenous (not	Not Reported

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

Triamcinolone Hexacetonide	S	otherwise specified)	Not Reported
Triamcinolone Hexacetonide	S	Other	Not Reported
Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16820459	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 3442			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Product Use Issue; Rheumatoid Arthritis; Vomiting	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Gold			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16833020	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028- 2933128-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Arava	C			Not Reported
	Plaquenil	C	Oral		Not Reported
	Prednisone	C			Not Reported
	Simponi	C			Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16878971	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2569757-00		77 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Arthritis	Humira			S	Subcutaneous			Not Reported
Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo Hydroxyquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17144108	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2800982-00		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthma;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Asthma; Chest Discomfort;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Chest X-Ray Abnormal;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Fall; Glaucoma; Joint Swelling; Macular Degeneration;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Musculoskeletal Disorder;	Humira			S	Subcutaneous	Citrate Free		Not Reported
Musculoskeletal Pain;	Prednisone			S	Unknown			Not Reported
Nausea; Pneumonia;	Plaquenil			S	Unknown			Not Reported
Pyrexia; Respiratory Tract Infection Bacterial; Retinal Toxicity; Rib Fracture;	Sulfasalazine			S	Unknown			Not Reported
Therapeutic Response Shortened; Wheelchair User; White Blood Cell Count Increased	Iron			C	Unknown			Not Reported
	Folic			C	Unknown			Not Reported
	Eliquis			C				Not Reported
	Prilosec			C				Not Reported
	Zantac			C				Not Reported
	Losartan			C				Not Reported
	Flexeril			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17153987	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.-2019CA027344			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Abnormal; Off Label Use;	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported

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

Product Use In Unapproved Indication	Pantoprazole	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Morphine Sulfate	S	Unknown	Unk	Not Reported
	Morphine Hydrochloride	S	Unknown	Unk	Not Reported
	Cefixime	S	Unknown	Unk	Not Reported
	Imuran [Azathioprine]	S	Oral	100 Milligram	Not Reported
	Nifedipine	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Rivotril	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported
	Zopiclone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17324085	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-005924		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	

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

Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified) Unk	Not Reported
Rituximab	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17439290	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-011929		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Toxic Skin Eruption	Coumadine			S	Oral	Unk		Bristol Myers Squibb	
	Innohep			S	Oral	Unk		Not Reported	
	Omnipaque			S	Intravenous (not otherwise specified)	55 Milliliter		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Kardegic			S	Oral	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17530620	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021584			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosis; Wound	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17549765	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2020-013114		29 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Atorvastatin	S	Unknown	Unk	Not Reported
	Clopidogrel	S	Unknown	Unk	Aurobindo
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Warfarin	S	Unknown	Unk	Not Reported
	Apixaban	S	Unknown	Unk	Not Reported
	Rivaroxaban	S	Unknown	Unk,6 Months	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563119	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022177		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			C	Unknown	2 Dosage Form, Qd		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown			Not Reported
	Estrojel			C	Unknown	1 Dosage Form, Qd		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported
	Valsartan			C	Unknown	320 Milligram, Qd		Not Reported
	Xalatan			C	Ophthalmic	50 Microgram, Qd		Not Reported

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Zingiber Officinale

C

Oral

500 Milligram

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022138			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aluminum Acetate			C	Unknown			Not Reported
	Atacand			C	Unknown			Not Reported
	Benzethonium Chloride			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	Neurontin			C	Unknown	600 Milligram, 3 Every 1 Day		Not Reported
Premarin			C	Unknown			Not Reported	
Tylenol			C	Unknown	650 Milligram, 2 Every 1 Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563481	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566876		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Bone Swelling; Candida Infection; Condition Aggravated;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous Solution	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C		Not Reported
	Simponi	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566890			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rituximab			S	Unknown			Not Reported
Acne Cystic; Condition Aggravated;	Anakinra			S	Unknown			Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Insomnia; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Orencia	S	Unknown		Not Reported
	Vioxx	S	Unknown		Not Reported
	Naproxen	S	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563528	EXPEDITED (15-DAY)		HO, LT, OT	PT-ACCORD-176291		50 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Tamponade;	Mycophenolic Acid			S	Unknown	2.5 G, Qd		Accord
Cardiogenic Shock;	Bosentan			S	Oral	250 Mg, Qd		Not Reported
Cardiomegaly;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
Concomitant Disease	Prednisolone			S	Unknown	5 Mg, Qd		Not Reported
Aggravated; Dyspnoea	Remodulin Sq			S	Subcutaneous	0.046 Mg, Q1hour		Not Reported
Exertional; Dyspnoea	Riociguat			C	Unknown	6 Mg, Qd		Not Reported
Paroxysmal Nocturnal;								
Electrocardiogram Qrs								
Complex Abnormal; Heart								
Sounds Abnormal;								
Oedema Peripheral;								
Pericardial Drainage;								
Pericardial Effusion;								
Pericardiotomy; Pleural								
Effusion; Prohormone								
Brain Natriuretic Peptide								
Increased; Rales; Serositis								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563805	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022560			Male	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17563950	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571269			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564021	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001710			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Tenderness; Chest Pain; Cough; Decreased Appetite; Dyspnoea; Herpes Simplex Hepatitis; Lethargy; Lymphopenia; Musculoskeletal Chest Pain; Nausea; Somnolence; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Bid, Tablet		Concordia	
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported	
	Metronidazole			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564032	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP008890			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Intolerance; Maculopathy; Pneumonia; Product Use Issue; Visual Impairment	Leflunomide			S	Oral	10 Mg, Qd		Apotex	
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex	
	Methotrexate			C	Subcutaneous	20 Mg, Unk		Not Reported	
	Sulfasalazine			C	Unknown	500 Mg, Qd		Not Reported	
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564060	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573629-00		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Pancreatitis; Product Use Issue	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	

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

	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Amitriptyline	C		Not Reported
	Hydromorph Contin	C		Not Reported
	Lyrica	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564141	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1432			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cystitis; Hepatitis B Reactivation; Inflammation; Malaise; Stomatitis; Weight Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022599			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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

Rituximab	S	otherwise specified)	Not Reported
Simponi	S	Intravenous drip Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2566946			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564456	EXPEDITED (15-DAY)		OT	CA-SA-2020SA067248			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain; Diarrhoea; Diarrhoea; Nausea; Renal Failure	Leflunomide			S		20 Mg, Qd		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17565635	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022535		43 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Orencia			S	Unknown	200 Milligram		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	10 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	20 Unk		Not Reported
	Prednisone			S	Unknown	20 Nanogram		Not Reported
	Rituximab			S	Intravenous drip	2 Gram		Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Unk		Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17566118	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR- APL-2019-095261		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C- Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Entesopathy; Erythema; Granuloma Skin; Headache;	Alendronic Acid			S	Unknown	70 Milligram, 4 Every 1 Week		Aurobindo
	Apo-Alendronate			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Apo-Ibuprofen			S	Oral	Unk		Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Methotrexate			S	Oral	10 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	12 Milligram, Every Week		Not Reported
	Apo-Methotrexate			S	Subcutaneous	10 Milligram, Every Week		Not Reported

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Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Apo-Methotrexate	S	Subcutaneous	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	17.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Subcutaneous	70 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram, Every Week	Not Reported
	Apo-Methotrexate	S	Unknown	17.5 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	10 Milligram, Four In One Week	Not Reported
	Apo-Methotrexate	S	Unknown	12.5 Milligram, Four In One Week	Not Reported
	Apremilast	S	Unknown	60 Milligram, Two Times A Day	Not Reported
	Apremilast	S			Not Reported
	Apremilast	S			Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Two Every One Week	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Oral	600 Milligram	Not Reported
	Ibuprofen	S	Unknown	600 Milligram, Once A Day	Not Reported
	Ibuprofen	S	Unknown	Unk, Once A Day	Not Reported

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Infliximab	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Motrin	S	Oral	600 Mg, Qd	Not Reported
Motrin	S	Oral	Unk Unk, Qd	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S			Not Reported
Otezla	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Tocilizumab	S	Unknown	360 Milligram,One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Milligram,One Every Four Week	Not Reported
Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Humira	C	Unknown	40 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram,Four Every 1	Not Reported

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

Methotrexate	S	Subcutaneous	Week 17.5 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	10 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	12 Milligram, Four Every 1 Week	Not Reported
Methotrexate	S	Unknown	70 Milligram, Every Week	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	C	Unknown	680 Milligram	Not Reported
Tocilizumab	C	Unknown	360 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Two Times A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17566974	EXPEDITED (15-DAY)		OT	NVSC2020CA079201			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Eye Disorder; Off Label Use; Psoriasis; Rash; Rheumatoid Arthritis; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hidroxicloroquina			S	Unknown	Unk		Not Reported

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Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Arava	C	Unknown	Unk	Not Reported
Desvenlafaxine Succinate	C	Unknown	Unk	Not Reported
Leflunomide	C	Oral	20 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Quetiapine Fumarate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17567557	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022569		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Vitamin D 3			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17567671	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA078923			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution)		Not Reported
	Stelara			S	Subcutaneous	Unk (Solution)		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17567912	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-022607		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

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

Myalgia; Pain; Pain In
Extremity; Peripheral
Swelling; Pulmonary
Toxicity; Rash Maculo-
Papular; Rash Pruritic;
Rheumatoid Lung;
Synovial Cyst; Synovitis;
Tenosynovitis; Treatment
Failure; Viral Upper
Respiratory Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17567934	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022780		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Orencia			S	Unknown			Bristol Myers Squibb	
Drug Ineffective; Feeling	Actemra			S	Unknown			Not Reported	
Abnormal; Insomnia; Pain	Apo-Prednisone			S	Unknown			Not Reported	
In Extremity; Peripheral	Arava			S	Unknown			Not Reported	
Swelling; Pneumonia;	Humira			S	Subcutaneous			Not Reported	
Rheumatoid Factor	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Increased; Rheumatoid	Methotrexate			S	Unknown			Not Reported	
Nodule; Somnolence;	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	
Weight Increased	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17568087	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022579		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label	Orencia			S	Unknown			Bristol Myers Squibb	
Use; Pancreatitis; Product	Humira			S	Subcutaneous			Not Reported	
Use Issue	Methotrexate			S	Subcutaneous	25.0 Milligram		Not Reported	

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

Plaquenil S	S	Unknown	200.0 Milligram, Qwk	Not Reported
Amitriptyline	C	Unknown		Not Reported
Hydromorph Contin	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17568106	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022615		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Orencia			S	Unknown			Bristol Myers Squibb
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported
Alopecia; Arthralgia; Bone	Enbrel			S	Unknown			Not Reported
Pain; Burning Sensation;	Humira			S	Subcutaneous			Not Reported
Choking; Cough; Drug	Hydroxychloroquine			S	Unknown			Not Reported
Ineffective; Drug	Methotrexate			S	Unknown	25.0 Milligram		Not Reported
Intolerance; Facial Pain;	Xeljanz			S	Oral	5.0 Milligram 2 Every 1		Not Reported
Fatigue; Fibromyalgia;						Days		
Headache; Hot Flush;	Xeljanz			S	Oral	5.0 Milligram 1 Every 1		Not Reported
Hypoaesthesia; Immune						Days		
System Disorder;	Morphine			C	Unknown			Not Reported
Insomnia; Joint Range Of	Tylenol			C	Unknown			Not Reported
Motion Decreased;								
Melanocytic Naevus;								
Nasal Discomfort; Nausea;								
Night Sweats;								
Oropharyngeal								
Discomfort; Pain; Pain In								
Extremity; Pain In Jaw;								
Peripheral Coldness;								
Rhinorrhoea; Skin Mass								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17568283	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA068487			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Drug	Hydroxychloroquine Sulfate			S				Sanofi

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

Ineffective	Leflunomide	S	Oral	20 Mg	Sanofi
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	17.5 Mg	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17568289	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068881			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S		200 Mg, Bid		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	15622307	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2557499-00		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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

Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Bupropion	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	15624381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556781-00		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

Sulfasalazine	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Meloxicam	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C		Not Reported
Prednisolone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	15625734	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557153-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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

Apo Prednison	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	15663999	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570464-00		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported

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

Plaquenil	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Rituximab	S		Not Reported
Lyrica	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	15683294	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573840-00		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling;	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Diclofenac			C				Not Reported
	Depo-Medrol			C	Intra-arterial			Not Reported

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

Pulmonary Toxicity; Rash	Xeljanz	C	Oral	Not Reported
Maculo-Papular; Rash	Prednisone	C	Unknown	Not Reported
Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure	Pantoprazole Magnesium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	16718423	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2892907-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	17563703	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3328160-00		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Pneumothorax	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Tylenol			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	17567968	EXPEDITED (15-DAY)		OT	GB-MACLEODS PHARMACEUTICALS US LTD-MAC2020025732			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Clopidogrel Atorvastatin Apixaban Warfarin Rivaroxaban Hydroxychloroquine	S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk Unk	Macleods Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	17572435	DIRECT					39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Unilateral	Hydroxychloroquine	Y		S			6 MTH	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	13186699	EXPEDITED (15-DAY)		OT	CA-ROCHE-1888735		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Rheumatoid Arthritis; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate Sodium			S	Oral			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
	Hydroxychloroquine Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	14906435	EXPEDITED (15-DAY)		OT	CA-ABBVIE-16K-028- 1678150-00		54 YR	Female	CAN

FDA Adverse Event Reporting System

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Tylenol			S	Unknown	Dosage Maintained		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Apo-Acetaminophen			S	Unknown			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Methotrexate			C				Not Reported	
	Meloxicam			C	Unknown			Not Reported	
	Synthroid			C				Not Reported	
	Tylenol No. 3			C				Not Reported	
	Celebrex			C				Not Reported	
	Acetaminophen And Codeine Phosphate			C				Not Reported	
	Hydromorphone Hcl			C				Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	14921809	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		75 YR	Female	CAN

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BMS-2018-043962

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Gold			S	Unknown			Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported
	Humira			S	Unknown	200 Milligram, Bid		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	200 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported
	Remicade			S	Unknown	200 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Anakinra			C	Unknown	100 Mg, Unk		Not Reported
	Ativan			C	Unknown	1 Gram, Qd		Not Reported
	Ativan			C	Unknown	1 Milligram		Not Reported

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Codeine	C	Unknown		Not Reported
Desoximetasone	C	Oral	Unk	Not Reported
Desoximetasone	C	Intramuscular	Unk	Not Reported
Desoximetasone	C	Intra-articular	Unk	Not Reported
Dexamethasone	C	Unknown		Not Reported
Dilaudid	C	Unknown	4 Milligram, Qid	Not Reported
Dilaudid	C	Unknown	4 Milligram, Qd	Not Reported
Diphenhydramine	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Enablex [Darifenacin]	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	40 Mg, Unk	Not Reported
Lasix [Furosemide]	C	Unknown	40 Milligram, Tid	Not Reported
Loperamide	C	Unknown	2 Milligram, Bid	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omniaris	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C	Unknown	200 Milligram	Not Reported
Vagifem	C	Vaginal		Not Reported
Dyclonine Hydrochloride	C	Unknown	Unk	Not Reported
Benadryl Cold	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Unk, Prn	Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported

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Rituximab			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	15328456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175439			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	15683363	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2574500-00		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatic Disorder; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Aspirin			C				Not Reported	

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Cymbalta	C	Not Reported
Hydromorphone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	17530404	EXPEDITED (15-DAY)		OT	NVSC2020CA070217			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Otezla			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Stelara			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	17533813	EXPEDITED (15-DAY)		OT	NVSC2020CA069732		36 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	1 Df		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	50 Mg		Not Reported
	Zingiber Officinale			C	Oral	500 Mg		Not Reported
	Zingiber Officinale			C	Unknown	500 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Xalatan			C	Ophthalmic	50 Mg, Qd		Not Reported
	Valsartan			C	Unknown	320 Mg, Qd		Not Reported
	Potassium Chloride			C	Unknown	1500 Mg, Qd		Not Reported
	Morphine			C	Unknown	Unk		Not Reported
	Jamp K20			C	Unknown	1500 Mg, Qd		Not Reported
	Gravol			C	Unknown	500 Mg		Not Reported
	Furosemide			C	Unknown	40 Mg, Qd		Not Reported

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Estrogel	C	Unknown	1 Df, Qd	Not Reported
Estrogel	C	Unknown	0.6 % Tid	Not Reported
Estradiol	C	Unknown	0.6 % Tid	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qw	Not Reported
Ergocalciferol	C	Unknown	Unk Unk, Qd	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate Calcium	C	Unknown	Unk Unk, Bid	Not Reported
Acetaminophen	C	Unknown	500 Mg, Qd	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	17542710	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA071289		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

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	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown		Not Reported
	Erythromycine	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	17545270	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-020929			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Somnolence; Visual Impairment	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram		Not Reported
	Tylenol			S	Unknown			Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	17569409	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022556		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Amino transferase Increased; Aspartate Amino transferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown	680 Milligram		Not Reported	
	Actemra			S	Unknown	360 Milligram 1 Every 1 Months		Not Reported	
	Alendronate			S	Unknown	70 Milligram 1 Every 1 Weeks		Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Unknown	25 Milligram		Not Reported	
	Humira			S	Unknown	40 Milligram		Not Reported	
	Methotrexate			S	Unknown	12.5 Milligram 1 Every 1 Weeks		Not Reported	
	Methotrexate			S	Unknown	12.0 Milligram 1 Every 1 Weeks		Not Reported	
	Methotrexate			S	Unknown	10.0 Milligram 1 Every 1 Weeks		Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Unknown	1000 Milligram 2 Every 1 Days		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous	10 Milligram 1 Every 1 Weeks		Not Reported	
	Methotrexate			S	Subcutaneous	17.5 Milligram 1 Every 1 Weeks		Not Reported	
	Methotrexate			S	Subcutaneous	15.0 Milligram 1 Every 1 Weeks		Not Reported	

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Methotrexate	S	Oral	10 Milligram 1 Every 1 Weeks	Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	11865597	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2012292491		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Enbrel			S				Pfizer	
	Xeljanz			S	Oral	5 Mg, 2x/Day (Q12h)		Pfizer	
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Xeljanz			S	Oral	10 Mg, Daily (2 In 1 Day)		Pfizer	
	Xeljanz			S		12.5 Mg, Unk		Pfizer	
	Xeljanz			S	Oral	5 Mg, 1x/Day Qd (1 Every 1 Day)		Pfizer	
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Aleve			S	Unknown	Unk		Not Reported	

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Adalimumab	S	Subcutaneous	Unk	Not Reported
Apo-Leflunomide	S	Oral	5 Mg, 2x/Day (Q12h)	Not Reported
Apo-Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		400 Milligram	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Naproxen	S		Unk	Not Reported
Leflunomide	S	Unknown	Unk Unk, Cyclical (1 Every Two Days)	Not Reported
Leflunomide	S	Unknown	Unk Unk, Bid	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hcq	C		Unk	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported

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Insulin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	20 Milligram	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	12769492	EXPEDITED (15-DAY)		CA, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-076352			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Orencia			S	Endocervical	Unk		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk, 2 Times/Wk		Not Reported
	Enbrel			S	Unknown	Unk, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported
	Naproxen			S	Oral	500 Mg, Bid		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Vioxx			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Oral	500 Milligram, Bid		Not Reported
	Naprosyn [Naproxen]			S	Unknown	500 Milligram, 2 Times/Wk		Not Reported
	Naproxen Sodium			S	Oral	500.0 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

Leflunomide	S	Unknown	20 Milligram	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Leflunomide	C	Unknown	10 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	13147266	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-005239		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill- Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Off Label Use; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Toradol			S	Unknown			Not Reported
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	13251292	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX- 2017AP006546		50 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Hernia; Joint Destruction; Nausea; Rheumatoid Arthritis; Stoma Complication	Hydroxychloroquine			S	Oral	400 Mg, Bid		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Prednisone			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown	Unk		Apotex	
	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Oral	200 Mg, Bid		Not Reported	
	Methotrexate Sodium			S	Subcutaneous	0.8 MI, Q.Wk.		Not Reported	
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	14235040	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2017AP021690		80 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Drug Hypersensitivity; Drug Ineffective; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Oral	20 Mg, Qd		Apotex	
	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported	
	Adalimumab			S				Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported	
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported	
	Sulfasalazine			S	Unknown	500 Mg, Qid		Not Reported	
	Arava			C	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported	
	Xeljanz			C	Oral	50 Mg, Bid		Not Reported	
Hydroxychloroquine Sulfate			C	Oral	Unk		Not Reported		

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	14238496	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021706			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Q.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Varenicline Tartrate			S	Oral	1 Df, Qd		Not Reported
	Varenicline Tartrate			S				Not Reported
	Acetaminophen W/Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium W/Naproxen			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported
	Tofacitinib Citrate			C	Unknown	Unk		Not Reported
	Valtrex			C	Unknown	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	14239514	EXPEDITED (15-DAY)		HO, OT	CA-PURDUE PHARMA-CAN-2016-0006553		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Adverse Reaction; Blood	Oxycontin	S	Unknown	Unk	Purdue
Creatinine Increased;	Actemra	S	Intravenous (not	488 Mg, Monthly	Not Reported
Blood Magnesium			otherwise specified)		
Increased; Blood	Arava	S	Oral	20 Mg, Daily	Not Reported
Potassium Increased;	Celebrex	S	Oral	Unk	Not Reported
Cyst; Deafness	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
Neurosensory; Diarrhoea;	Fentanyl	S	Unknown	Unk	Not Reported
Diarrhoea; Drug	Gabapentin	S	Oral	100 Mg, Bid	Not Reported
Hypersensitivity; Drug	Methotrexate Sodium	S	Subcutaneous	Unk Unk, Weekly	Not Reported
Ineffective; Drug	Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
Ineffective; Drug	Orencia	S	Intravenous (not	750 Mg, Monthly	Not Reported
Intolerance; Dry Eye;			otherwise specified)		
Epigastric Discomfort;	Orencia	S	Intravenous (not	750 Mg, 1 Every 3 Weeks	Not Reported
Fatigue; Gastrointestinal			otherwise specified)		
Disorder; Gastrointestinal	Plaquenil /00072602/	S	Unknown	400 Mg, Daily	Not Reported
Disorder; Hospitalisation;	Sulfasalasin	S	Oral	2.5 G, Daily	Not Reported
Hypersensitivity; Infection;	Acetaminophen W/Oxycodone	C		1 Df, Prn	Not Reported
Nausea; Osteoarthritis;	Aclasta	C	Intravenous (not	750 Mg, Monthly	Not Reported
Osteopenia; Pleural			otherwise specified)		
Fibrosis; Pleural	Actonel	C	Unknown	36 Mg, Weekly	Not Reported
Thickening; Presbycusis;	Ascorbic Acid	C	Unknown	Unk	Not Reported
Renal Impairment; Skin	Biotin	C	Unknown	Unk	Not Reported
Lesion; Skin Lesion; Sleep	Calcium	C	Unknown	Unk	Not Reported
Disorder; Treatment	Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Failure	Tocopherol	C	Unknown	Unk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Daily	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Daily	Not Reported
	Ergocalciferol	C	Unknown	Unk Unk, Daily	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported

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

Ferrous Gluconate	C	Unknown	300 Mg, Daily	Not Reported
Loperamide Hcl	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Pantoprazole	C	Unknown	40 Mg, Daily	Not Reported
Prednisone	C	Unknown	5 Mg, Daily	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Daily	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Daily	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	14757583	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009592			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Hydroxychloroquine			S	Unknown	Unk		Apotex
Drug Intolerance; Impaired	Leflunomide			S	Unknown	Unk		Apotex
Work Ability; Middle	Penicillin			S	Unknown	Unk		Apotex
Insomnia; Rheumatoid								
Arthritis; Rheumatoid								

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

Nodule; Synovitis; White Blood Cell Count Decreased	Acetylsalicylic Acid	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Aspirin /00002701/	S	Unknown	Unk	Not Reported
	Penicillin G /00000901/	S	Unknown	Unk	Not Reported
	Penicillin G Potassium	S	Unknown	Unk	Not Reported
	Penicillin G Procaine	S	Unknown	Unk	Not Reported
	Pregabalin	C	Unknown	Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine Phosphate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	15619609	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555410-00		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	11 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

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

Sodium Aurothiomalate	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	15623842	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557025-00		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Humira			S	Subcutaneous			Not Reported
Emotional Disorder;	Actemra			S	Unknown			Not Reported
Herpes Zoster;	Enbrel			S	Subcutaneous			Not Reported
Hypothyroidism; Immobile;	Hydroxychloroquine			S	Oral			Not Reported
Inappropriate Schedule Of	Methotrexate			S	Oral			Not Reported
Product Administration;	Methotrexate			S	Ophthalmic			Not Reported
Injury; Lymphadenectomy;	Rituxan			S	Intravenous (not			Not Reported
Malignant Melanoma;					otherwise specified)			
Mobility Decreased;	Sulfasalazine			S	Oral			Not Reported
Product Dose Omission;	Apo-Hydroxyquine			S	Unknown			Not Reported
Product Dose Omission;	Folic Acid			C	Unknown			Not Reported
Rheumatoid Arthritis;	Prednisone			C	Oral			Not Reported
Therapeutic Product Effect	Restasis			C	Unknown			Not Reported
Incomplete; Toe	Synthroid			C	Unknown			Not Reported
Amputation; Victim Of	Xeljanz			C	Unknown			Not Reported
Crime	Vitamins Nos			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	15629783	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557408-00		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Ankle Fracture; Anti-Cyclic Citrullinated Peptide	Humira	S	Subcutaneous	Not Reported
Antibody Positive;	Actemra	S	Unknown	Not Reported
Arthralgia; Asthenia; Bone Density Abnormal;	Arava	S	Unknown	Not Reported
Decreased Appetite;	Cimzia	S	Subcutaneous	Not Reported
Disability; Drug Ineffective;	Enbrel	S	Subcutaneous	Not Reported
Headache;	Methotrexate	S	Subcutaneous	Not Reported
Hypercholesterolaemia;	Methotrexate	S	Oral	Not Reported
Infection; Joint Stiffness;	Methotrexate	S	Subcutaneous	Not Reported
Joint Swelling; Malaise;	Methotrexate	S	Subcutaneous	Not Reported
Mood Swings;	Orencia	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Nausea; Neck Deformity; Neck Mass; Pain;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress;	Simponi	S	Subcutaneous	Not Reported
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Sulfasalazine	S	Oral	Not Reported
Treatment Failure;	Apo-Hydroxyquine	S	Unknown	Not Reported
Unevaluable Event;	Apo-Leflunomide	S	Unknown	Not Reported
Vomiting	Apo-Prednisone	S	Oral	Not Reported
	Indometacin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Cymbalta	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	16357705	EXPEDITED (15-DAY)			CA-ORION CORPORATION ORION PHARMA-TREX2019-1532			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Hyperhidrosis;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	

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

Inappropriate Schedule Of Product Administration; Nausea; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Estradot	S	Transdermal	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	16473931	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1994		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Inflammation; Joint Stiffness; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

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

Rituxan	S	otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cimzia	S	Unknown	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Tocilizumab	S	Unknown	Not Reported
Abatacept	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Adalimumab	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rabeprazole Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	16857402	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574079-00		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Humira			S	Subcutaneous			Not Reported
Contraindicated Product Administered; Rash;	Actemra			S	Unknown			Not Reported
Treatment Failure;	Apo-Hydroxyquine			S	Unknown			Not Reported

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

Urticaria	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17529190	EXPEDITED (15-DAY)		OT	NVSC2020AU065740			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Eye Movement Disorder; Mobility Decreased; Scleroderma	Tacrolimus			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	10 Mg, Unknown		Not Reported
	Prednisone			S	Unknown	Up To 50 Mg		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	0.25 Mg/Kg, Unknown		Not Reported
	Prednisolone			S	Unknown	1 Mg/Kg, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569440	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023131			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023149			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Orencia			S	Unknown			Bristol Myers Squibb	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Rituximab			S	Endocervical			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569480	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- 202003001670			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Hepatic Enzyme Increased	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Arava			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	1000 Mg, Bid		Not Reported	
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
	Gliclazide			C		Unk		Not Reported	
	Vimovo			C		Unk		Not Reported	

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

Rabeprazole	C	Unk	Not Reported
Mr	C	Unk	Not Reported
Metformin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569650	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022575		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Q4wk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Alendronate			S	Unknown	70 Milligram, Qwk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
	Humira			S	Unknown	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	12 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	50 Milligram, Qmo		Not Reported
	Rituximab			S	Intravenous drip	1000 Milligram, Bid		Not Reported

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

Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569669	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023123			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	2 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569671	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022648		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569754	EXPEDITED (15-DAY)		HO	CA-ROCHE-2565726		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naprosyn [Naproxen]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569843	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022714		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbycusis; Renal Impairment; Skin Lesion; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Unk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	488 Milligram, Qmo	Not Reported
	Arava	S	Intravenous (not otherwise specified)	20 Milligram, Qd	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Fentanyl	S	Unknown	Unk	Not Reported
	Gabapentin	S	Unknown	100 Milligram, Bid	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q3wk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	2.5 Gram, Qd	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
	Ascorbic Acid	C	Unknown	Unk	Not Reported
	Biotin	C	Unknown	Unk	Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
	Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
	Ferrous Fumarate	C	Unknown	300 Milligram	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Hydroxocobalamin	C	Unknown	Unk	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
	Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
	Nicotinamide	C	Unknown	Unk	Not Reported
	Nortriptyline Hydrochloride	C	Oral	40 Milligram, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Milligram	Not Reported

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Prednisone	C	Unknown	5 Gbq 1 Every 1 Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qd	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Tylenol	C	Unknown	1000 Milligram, Qd	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Vitamin C [Ascorbic Acid]	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569878	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1453			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Drug Ineffective	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1451			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)	S	Unknown	Not Reported
	Atorvastatin Calcium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Alprazolam	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Naprosyn	C	Unknown	Not Reported
	Pantoloc	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570139	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201611-005804			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Unk		Concordia
	Arava			S	Oral	10 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Every Other Week		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg (Tablet)		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Prednisone			S	Endocervical	20 Mg, Qd		Not Reported
	Rituxan			S	Intravenous (not	2 G,Qcy; Iv Nos		Not Reported

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

				otherwise specified)					
	Rituxan		S	Unknown	2 Unk, Qcy; Unknown				Not Reported
	Sulfasalazine		S	Oral	500 Mg, Bid				Not Reported
	Sulfasalazine		S	Unknown	1000 Mg, Bid				Not Reported
	Sodium Aurothiomalate		S	Intramuscular	Unk				Not Reported
	Methotrexate		S	Subcutaneous	20 Mg				Not Reported
	Methotrexate		S	Unknown	Unk				Not Reported
	Rituximab		S	Intravenous (not otherwise specified)	2 G, Q6m; Iv Nos				Not Reported
	Etanercept		S		50 Mg, Weekly				Not Reported
	Methotrexate		C						Not Reported
	Prednisone		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570142	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202001000092			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Dry Eye;	Hydroxychloroquine			S	Unknown	Unk		Concordia
Dry Mouth; Fatigue; Finger	Humira			S	Subcutaneous	Unk		Not Reported
Deformity; Impaired	Fentanyl			S	Unknown	Unk		Not Reported
Driving Ability; Macular	Levothyroxin			C		Unk		Not Reported
Degeneration; Pain In	Raloxifene			C		Unk		Not Reported
Extremity; Rheumatoid	Lidoderm			C		Unk		Not Reported
Arthritis; Rheumatoid								
Nodule; Somnolence								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570259	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023559			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
Antibody Test Positive;								
Arthralgia; Arthritis; Body								

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

Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Therapy Non- Responder; Vomiting; Wheelchair User	Orencia Actemra Actemra Anakinra Anakinra Apo-Naproxen Apo-Prednisone Enbrel Humira Hydroxychloroquine Infliximab Methotrexate Sulfasalazine Triamcinolone Triamcinolone Methotrexate Folic Acid	S S S S S S S S S S S S S S S S S C	Unknown Intravenous (not otherwise specified) Unknown Subcutaneous Unknown Unknown Oral Subcutaneous Unknown Oral Intravenous (not otherwise specified) Subcutaneous Oral Intra-articular Unknown Unknown Unknown	280 Milligram, Q2wk Unk Unk, Qd 3 Milligram, Bid 12.5 Milligram, Qwk Unk Unk, Qd 3 Milligram, Qwk 15 Milligram, Qwk 250 Milligram, Qd 	Bristol Myers Squibb Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068781			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Interstitial Lung Disease; Rash	Leflunomide Plaquenil			S S	 Oral	10 Mg 200 Mg, Q12h		Sanofi Sanofi	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570308	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068804			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective; Interstitial Lung Disease	Leflunomide	S	Unknown	Unk				Sanofi	
	Plaquenil	S	Unknown	400 Mg				Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570311	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068793			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Hepatotoxicity; Rash; Treatment Failure	Leflunomide			S				Sanofi	
	Hydroxychloroquine Sulfate			S		1 Df		Sanofi	
	Adalimumab			S	Subcutaneous			Not Reported	
	Azathioprine			S		1 Df		Not Reported	
	Orencia			S	Subcutaneous	125 Df, Qw		Not Reported	
	Methotrexate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570367	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023442		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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

Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Rituximab	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Other	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570370	EXPEDITED (15-DAY)		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2020-01473		52 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nocardiosis	Hydroxychloroquine			S	Unknown	0.2 Gram, Bid		Lupin	
	Prednisone			S	Unknown	60 Milligram, Qd		Not Reported	
	Prednisone			S	Unknown	50 Milligram, Qd		Not Reported	
	Prednisone			S	Unknown	20 Milligram, Qd In 2 Weeks		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570449	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028- 2500975-00		50 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Abdominal Pain Upper;	Methotrexate			S	Unknown			Not Reported
Alopecia; Arthralgia; Bone	Hydroxychloroquine			S	Unknown			Not Reported
Pain; Burning Sensation;	Enbrel			S	Unknown			Not Reported
Choking; Cough; Drug	Actemra			S	Unknown			Not Reported
Ineffective; Drug	Orencia			S	Unknown			Not Reported
Ineffective; Drug	Xeljanz			S	Oral			Not Reported
Ineffective; Drug	Xeljanz			S	Oral			Not Reported
Ineffective; Drug	Xeljanz			S	Oral			Not Reported
Intolerance; Drug	Synthetic Morphine			C	Unknown	Unknown Dose 1 Or 2		Not Reported
Intolerance; Facial Pain;	Tylenol			C		Unknown Hs		Not Reported
Fatigue; Fibromyalgia;								
Headache; Hot Flush;								
Hypoaesthesia; Immune								
System Disorder;								
Insomnia; Joint Range Of								
Motion Decreased;								
Lipoma; Melanocytic								
Naevus; Nasal Discomfort;								
Nausea; Night Sweats;								
Oropharyngeal								
Discomfort; Osteoporosis;								
Pain; Pain In Extremity;								
Pain In Jaw; Peripheral								
Coldness; Platelet Count								
Decreased; Rhinorrhoea;								
Skin Mass								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571132		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rituxan			S	Intravenous (not			Not Reported
Arthralgia; Drug					otherwise specified)			
Ineffective; Joint Swelling;	Enbrel			S	Unknown			Not Reported
Malaise; Mobility								

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

Decreased; Musculoskeletal Stiffness; Osteomyelitis; Pain; Rheumatoid Arthritis; Rheumatoid Lung; Rheumatoid Nodule; Therapeutic Product Effect Decreased	Enbrel Enbrel Methotrexate Plaquenil [Hydroxychloroquine Sulfate] Remicade Arava Leflunomide Xeljanz Xeljanz Xr Xeljanz Xr Xeljanz Xr	S S S S S C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Oral Oral Unknown Oral	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570607	EXPEDITED (15-DAY)		OT	NVSC2020CA077910		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retinopathy	Hydroxychloroquine			S	Unknown	6.78 Mg/Kg (Cumulative Dose 1.24 Kg)		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570792	EXPEDITED (15-DAY)		OT	NVSC2020CA079412		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Synovitis	Cosentyx			S	Unknown	Unk		Novartis	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Otezla			S	Oral	Unk		Not Reported	

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Plaquenil	S	Unknown	Unk	Not Reported
Remicaide	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17571152	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118213			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate Sodium			S	Oral			Pfizer
	Methotrexate Sodium			S	Other	Unk		Pfizer
	Enbrel			S	Unknown			Pfizer
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17571244	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020118892			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S		20 Mg		Pfizer

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Plaquenil [Hydroxychloroquine Sulfate]		S		300 Mg		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17571456	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA079635		68 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Oral	75 Mg, Bid		Novartis	
	Apo Diclo			S	Oral	75 Mg, Bid		Not Reported	
	Apo Lisinopril			S	Oral			Not Reported	
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported	
	Diclofenac			S	Oral	75 Mg, Bid		Not Reported	
	Diclofenac Potassium			S	Oral	75 Mg, Prn		Novartis	
	Folic Acid			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Not Reported	
	Lisinopril			S	Unknown			Not Reported	
	Lisinopril Dihydrate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported	
	Pantoprazol			S	Unknown			Not Reported	
	Pantoprazol			S	Oral	Unk		Not Reported	
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported	
	Synthroid			S	Oral			Not Reported	
	Tecta			S	Oral			Not Reported	
	Xeljanz			S	Oral	10 Mg, Qd		Not Reported	
	Gold			C	Unknown			Not Reported	
	Depo-Medrol			C	Intramuscular			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17572087	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069054			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Test Abnormal; Inflammation; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Sanofi
	Plaquenil			S	Unknown	Unk		Sanofi
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17572198	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024000			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported

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Ilaris	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown 500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17572243	EXPEDITED (15-DAY)		OT	US-SA-2020SA071865			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium; Drug Interaction; Retinopathy; Visual Field Defect	Hydroxychloroquine Docetaxel Anastrozole			S S C				Sanofi Sanofi Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17572378	EXPEDITED (15-DAY)		OT	NVSC2020CA079465			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Cosentyx	S	Unknown	Unk	Novartis
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573060	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1029307			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Tamponade; Cardiogenic Shock; Serositis	Mycophenolate Mofetil			S	Unknown	2.5 Gram		Not Reported
	Bosentan			S	Unknown	250 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Mylan
	Prednisolone			S	Unknown	5 Milligram		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg/H, Continuing		Mylan
	Riociguat			C	Unknown	6 Milligram		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573076	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA079709		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug	Cosentyx			S	Unknown	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

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Intolerance; Drug				otherwise specified)		
Tolerance Decreased;	Apo-Leflunomide	S	Unknown	Unk		Not Reported
Infection; Off Label Use;	Enbrel	S	Unknown	Unk		Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown	Unk		Not Reported
Seronegative Arthritis;	Hydroxychloroquine	S	Unknown	Unk		Not Reported
Spinal Disorder;	Orencia	S	Unknown	Unk		Not Reported
Therapeutic Product Effect	Simponi	S	Subcutaneous	Unk		Not Reported
Decreased; Type 2	Sulfasalazine	S	Unknown	500 Mg, Bid		Not Reported
Diabetes Mellitus; Wound	Naprosyn	C	Unknown	Unk		Not Reported
Infection						

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573103	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1031278		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Hydroxychloroquine			S	Unknown	For 6 Weeks		Not Reported	
	Prednisone			S	Oral	1 Milligram/Kilogram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573142	EXPEDITED (15-DAY)		OT	NVSC2020CA079502		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug	Voltaren			S	Unknown	Unk		Novartis	
Ineffective; Eye Disorder;	Diclofenac Sodium			S	Unknown	Unk		Novartis	
Gait Disturbance; Gait	Diclofenac			S	Unknown	Unk		Novartis	
Inability; Joint Dislocation;	Diclofenac Potassium			S	Unknown	Unk		Novartis	
Stomatitis	Methotrexate			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Apo-Diclofenac			S	Unknown	Unk		Not Reported	

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Desoximetasonone	S	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573170	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023021		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unk, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, Q2wk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk, Q6wk		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573206	EXPEDITED (15-DAY)		OT	NVSC2020CA079493		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Voltaren Sr			S	Unknown	75 Mg, Prn		Novartis
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported

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Tecta	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Depo-Medrol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573227	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023154			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematousus	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Subcutaneous	1 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Topicort Lp			S	Topical	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023109		60 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported	
	Infliximab			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Sulfasalazine			S	Oral	Unk		Not Reported	
	Tocilizumab			S	Unknown	Unk		Not Reported	
	Methotrexate			C	Unknown	25 Milligram, Qwk		Not Reported	
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported	
	Desoximetasone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17573405	NON-EXPEDITED			NVSC2020US082232			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder	Hydroxychloroquine			S	Oral	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17581632	DIRECT					66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura	Plaquenil			S	Oral			Not Reported	
	Tirosint			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	13058057	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015766		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown	Unk		Apotex	
	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	13251448	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006660			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown			Apotex	
	Apo-Hydroxyquine			S				Apotex	
	Apo-Cyclosporine			S	Unknown			Apotex	
	Apo-Cyclosporine			S				Apotex	
	Apo-Azathioprine			S	Unknown	Unk		Not Reported	
	Apo-Azathioprine			S				Not Reported	

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Hydroxychloroquine	S	Unknown	Unk	Apotex
Hydroxychloroquine	S			Apotex
Cyclosporine	S	Unknown	Unk	Apotex
Cyclosporine	S			Apotex
Azathioprine	S	Unknown	Unk	Apotex
Azathioprine	S			Apotex
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Actemra	S	Unknown	640 Mg, Q.Wk.	Not Reported
Arava	S	Oral		Not Reported
Arava	S			Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Gold	S	Unknown		Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Humira	S	Unknown	400 Mg, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Imuran /00001501/	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Tocilizumab	S	Unknown	640 Mg, Q.Wk.	Not Reported
Tocilizumab	S			Not Reported

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24-Mar-2020	14498265	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-007254			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Off Label Use; Thyroid Disorder	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	15629234	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028- 2558776-00		21 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pneumonia; Rash;	Humira			S	Subcutaneous			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral	Dose Decreased		Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified) Intravenous Drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Synthroid	C	Unknown	Not Reported
	Codeine Phosphate	C		Not Reported

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Hydromorphone Hydrochloride
Celebrex

C Unknown
C Oral

Not Reported
Not Reported

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24-Mar-2020	15632850	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-105426		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	15689905	EXPEDITED (15-DAY)		HO, OT	CA-SAKK- 2018SA324553AA		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Anakinra			S		50 Mg, Qd		Not Reported

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Positive; Nausea; Obesity; Septic Shock; Vomiting	Humira Ac	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	5 Mg, Qd	Sanofi
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	15707284	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2584423-00		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	15712957	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2588343-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Iron Abnormal; Disease Progression; Drug	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

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

Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Certolizumab Pegol	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	16778722	EXPEDITED (15-DAY)		HO, OT	CA-ADVANSZ PHARMA-GSH201706-003601			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Arthralgia; Aspartate	Hydroxychloroquine			S	Oral	Unk		Concordia
Aminotransferase Increased; Basal Cell Carcinoma; Blood	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
Parathyroid Hormone Decreased; C-Reactive Protein Increased;	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	680 Mg, Monthly		Not Reported
	Actemra			S	Unknown	360 Mg, Monthly		Not Reported
	Actemra			S	Unknown	380 Mg, Unknown		Not Reported



Detailed Report

Contraindicated Product	Actemra	S	Unknown	360 Mg, Monthly	Not Reported
Administered; Drug Eruption; Drug	Alendronate Sodium	S	Unknown	70 Mg, Weekly	Not Reported
Hypersensitivity; Drug	Alendronate Sodium	S	Unknown	Unk	Not Reported
Hypersensitivity; Drug Ineffective; Drug	Codeine	S	Unknown	Unk	Not Reported
Intolerance; Drug	Enbrel	S	Unknown	25 Mg, Freq: 2 X 1 Week	Not Reported
Tolerance Decreased; Erythema; Erythema;	Enbrel	S	Unknown	50 Mg, Freq: 2 X 1 Week, Biw	Not Reported
Granuloma Skin; Hypercalcaemia;	Enbrel	S	Unknown	Unk	Not Reported
Hypersensitivity; Inflammation; Infusion	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
Related Reaction; Loss Of Personal Independence In Daily Activities;	Humira	S	Subcutaneous	40 Mg, Freq: 1 X 2 Weeks, Qow	Not Reported
Musculoskeletal Stiffness; Pain; Panniculitis;	Humira	S		40 Unk, Unk	Not Reported
Peripheral Swelling; Product Use Issue;	Humira	S	Subcutaneous	40 Mg Qow	Not Reported
Pruritus; Rash; Rash;	Methotrexate	S	Subcutaneous	10 Mg, Freq: Unk X 1 Weeks	Not Reported
Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid	Methotrexate	S	Oral	10 Mg, Freq: Unk X 1 Weeks	Not Reported
Arthritis; Rheumatoid Nodule; Skin Necrosis;	Methotrexate	S	Subcutaneous	15 Mg, Unk	Not Reported
Skin Ulcer; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Subcutaneous	17.5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Unknown	12 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Freq: Unk X 1 Weeks	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg Q4w	Not Reported
	Methotrexate	S	Unknown	12.5 Unk	Not Reported
	Methotrexate	S	Unknown	12 Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported

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

Methotrexate	S	Oral	10 Mg Q4w	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Oral	10 Mg Q4w	Not Reported
Methotrexate	S	Unknown	12 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Weekly	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	17.5 Mg, Weekly	Not Reported
Methotrexate	S	Unknown	15 Mg Q4w	Not Reported
Methotrexate	S	Unknown	12 Mg Q4w	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg Q4w	Not Reported
Methotrexate	S	Unknown	17 Unk	Not Reported
Methotrexate	S	Unknown	12.5 Unk, Q4w	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Orencia	S	Unknown	780 Mg, Unknown	Not Reported
Orencia	S	Unknown	780 Mg, Weekly	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk, Powder And Solvent For Intravesical Suspension	Not Reported
Remicade	S	Unknown	, Powder And Solvent For	Not Reported

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

			Intravenous (not otherwise specified)	Intravesical Suspensionunk	
Rituxan	S		1000 Mg, Bid		Not Reported
Rituxan	S	Unknown	Unk		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
Sulfasalazine	S	Unknown	Unk Mg		Not Reported
Sulfasalazine	S	Unknown	500 Mg		Not Reported
Myochrysine	S	Intramuscular	50 Mg, Monthly		Not Reported
Myochrysine	S	Intramuscular	25 Mg, Monthly		Not Reported
Myochrysine	S	Parenteral	50 Mg, Monthly		Not Reported
Methotrexate Sodium	S	Oral	10 Mg, Freq: 1 X 2 Weeks, Qow		Not Reported
Alendronic Acid	S	Unknown	70 Mg, Weekly		Not Reported
Rituximab	S	Unknown	1000 Mg, Bid		Not Reported
Tocilizumab	S	Unknown	680 Mg Q4w		Not Reported
Ciclosporin	C		Unk		Not Reported
Prednisolone	C				Not Reported
Prednisone	C		Unk		Not Reported
Prednisone	C		Unk		Not Reported
Xeljanz	C				Not Reported
Alendronate Sodium	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	16836959	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-27185		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Iron Abnormal; Condition	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

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

Aggravated; Contraindicated Product	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Administered; Diarrhoea;	Actemra	S	Unknown		Not Reported
Disease Progression;	Actemra	S	Unknown		Not Reported
Drug Hypersensitivity;	Actemra	S	Unknown		Not Reported
Drug Ineffective; Drug	Actemra	S	Unknown		Not Reported
Intolerance;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Hypersensitivity;	Actemra	S	Unknown	Unknown	Not Reported
Laryngeal Disorder;	Actemra	S	Unknown	Unknown	Not Reported
Nausea; Off Label Use;	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
Product Use Issue;	Arava	S	Oral	Unknown	Not Reported
Pruritus; Psoriatic	Arava	S	Unknown	Unknown	Not Reported
Arthropathy; Rash;	Arava	S	Unknown	Unknown	Not Reported
Rheumatoid Arthritis;	Azathioprine	S	Unknown	Unknown	Not Reported
Sciatica; Sinusitis;	Certolizumab Pegol	S	Unknown		Not Reported
Stomatitis; Therapeutic	Certolizumab Pegol	S	Unknown		Not Reported
Product Effect Incomplete;	Certolizumab Pegol	S	Unknown		Not Reported
Treatment Failure; Weight	Certolizumab Pegol	S	Unknown		Not Reported
Decreased	Ciclosporin	S	Oral	Unknown	Not Reported
	Ciclosporin	S	Oral	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Cimzia	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Humira	S	Unknown		Not Reported

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Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown	Unknown	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous	Unknown	Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported

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Prednisone			C	Unknown	Unknown	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	16977712	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201910001380			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Joint Swelling; Neutropenia; Pain In Extremity; Rash; White Blood Cell Count Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported	
	Methotrexate			S	Unknown	Unk, Weekly		Not Reported	
	Arava			S	Unknown	10 Mg, Qd		Not Reported	
	Arava			S	Unknown	20 Mg, Qd		Not Reported	
	Xeljanz			C		Unk		Not Reported	
	Flurbiprofen			C		Unk		Not Reported	
	Tylenol			C		Unk		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Prevacid			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17404137	EXPEDITED (15-DAY)		CA, HO, OT	NVSC2020CA032705		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Arthropathy; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound	Cosentyx			S	Unknown	Unk		Novartis	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Sulfasalazine			S	Unknown	500 Mg, Unknown		Not Reported	

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Infection	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Naprosyn	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574330	EXPEDITED (15-DAY)		DS, OT	CA-ADVANZ PHARMA-GSH201711-006281			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic), Plaquenil			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia
	Hydroxychloroquine			S	Unknown	300 Mg		Concordia
	Arava			S	Oral	10 Mg		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Every Other Week		Not Reported
	Orencia			S	Subcutaneous	250 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly; Solution		Not Reported
	Methotrexate			S	Unknown	12.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Weekly		Not Reported

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Methotrexate	S	Subcutaneous	15 Mg, Weekly	Not Reported
Salazopyrin	S	Unknown		Not Reported
Actemra	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Unknown	50 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Every Six Weeks	Not Reported
Orencia	S	Subcutaneous	25 Mg	Not Reported
Bifidobacterium Bifidum	C			Not Reported
Prednisone	C			Not Reported
Sulfasalazine	C			Not Reported
Celebrex	C			Not Reported
Loperamide	C			Not Reported
Pantoprazole	C			Not Reported
Xeljanz	C			Not Reported
Simponi	C			Not Reported
Wellbutrin	C			Not Reported
Plaquenil	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574349	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201709-005363			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Concordia
Abdominal Discomfort;	(Authorized Generic),Plaquenil							
Anti-Cyclic Citrullinated	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Concordia
Peptide Antibody; C-Reactive Protein	(Authorized Generic),Plaquenil							
Increased;	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
Contraindicated Product	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
Administered; Drug	Orencia			S	Unknown	Unk		Not Reported
Ineffective; Drug	Orencia			S	Subcutaneous	Unk		Not Reported
Ineffective; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)	125 Mg, Weekly		Not Reported
Joint Swelling; Joint Swelling; Leukopenia; Musculoskeletal Stiffness;								

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

Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment; Visual Impairment	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Weekly	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk, Solution Subcutaneous	Not Reported
	Methotrexate	C		Unk	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Acetaminophen	C		Unk	Not Reported
	Depo-Medrol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Tylenol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574376	EXPEDITED (15-DAY)		OT	CA-ADVANS PHARMA- GSH201805-001688			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia	
	Kevzara			S	Subcutaneous	20 Mg, Qow		Not Reported	
	Leflunomide			S	Oral	20 Mg		Not Reported	
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	

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

Methotrexate	S	Subcutaneous	25 Mg, Weekly	Not Reported
Cyclosporin	S	Intracardiac	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	162 Mg, Weekly	Not Reported
Xeljanz	C		Unk	Not Reported
Nexium	C		Unk	Not Reported
Metformin	C		Unk	Not Reported
Vitamin D	C		Unk	Not Reported
Magnesium	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574713	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023101		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	160 Milligram, Qwk		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

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

Rheumatoid Lung;
Synovial Cyst; Synovitis;
Tenosynovitis; Treatment
Failure; Viral Upper
Respiratory Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574715	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-013887			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate			S	Oral	35 Milligram, Every Week		Aurobindo	
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported	
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported	
	Mycophenolate Mofetil			S	Oral	500 Milligram, Two Times A Day		Not Reported	
	Mycophenolate Mofetil			S	Oral	1 Gram, Two Times A Day		Not Reported	
	Azathioprine			C	Oral	50 Milligram, Once A Day		Not Reported	
	Azathioprine			C	Oral	150 Milligram, Once A Day		Not Reported	
	Azathioprine			C	Oral	100 Milligram, Two Times A Day		Not Reported	
	Humira			C	Subcutaneous	40 Milligram (1 Every 2 Weeks)		Not Reported	
	Ketoprofen			C	Unknown	Unk		Not Reported	
	Methotrexate			C	Oral	Unk		Not Reported	
	Methotrexate			C	Subcutaneous	25 Milligram, Every Week		Not Reported	
	Prolia			C	Subcutaneous	60 Milligram (1 Every 6 Months)		Not Reported	
	Rituximab			C	Intravenous (not otherwise specified)	1 Gram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574931	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- 202003001751			Unknown	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	300-400 Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575142	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB- 000867			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Headache; Hyperhidrosis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Ipca
	Prednisolone			C	Unknown	Unk, Take As Directed		Not Reported
	Dermol			C	Unknown	Unk, Use As Directed		Not Reported
	Dermovate			C	Unknown	Unk, Apply 1-2 Times/Day Thinly To All Affected Areas		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575254	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023112		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	20 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported

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

Methotrexate	S	Subcutaneous	20 Milligram, 4 Every 1 Week	Not Reported
Prednisone	S	Oral	5 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575456	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023128			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Intentional Product Use Issue; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft Tissue Swelling; Synovitis	Orencia			S	Intracavernous			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk, 2 Every 1 Day		Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Diphenhydramine			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Kadian			C	Unknown			Not Reported
	Kenalog [Triamcinolone Acetonide]			C	Intra-articular			Not Reported
	Oxyneo			C	Unknown			Not Reported

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

Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C	Unknown	Not Reported
Vagifem	C	Vaginal	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575525	NON-EXPEDITED			US-PFIZER INC-2020123929		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Therapeutic Product Effect Incomplete	Sulfasalazine			S	Oral	500 Mg, 2x/Day		Pfizer	
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported	
	Xeljanz Xr			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575752	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023400		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported	
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported	
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported	
	Xeljanz			C	Oral	5 Gram		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575760	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020120639			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Cosentyx			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575864	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567757		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Lyrica			C	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17576314	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023435		49 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Dyspnoea; Gait Disturbance; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non- Responder; Tuberculin Test Positive	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral	200 Milligram, Bid		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tramadol			C	Unknown	100 Milligram		Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17576658	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023436			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage;	Orencia			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	4 Milligram/Kilogram		Not Reported
	Arava			S	Unknown	10 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qd		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

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

Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Unknown		Not Reported
	Prednisone	C	Unknown	50 Milligram, 1 Every 1 Day	Not Reported
	Prevacid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	50 Milligram, 2 Every Q Days	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577389	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023448		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Golimumab			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Nystatin			S	Unknown			Not Reported	
	Nystatin			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tramadol			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Indometacin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577584	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

BMS-2020-023530

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577628	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023475		55 YR	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Qd		Not Reported

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

Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577694	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023552		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Allergic; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Septra			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577757	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023607		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Pneumonia Viral; Soft	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qd		Not Reported

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

Tissue Disorder; Synovitis; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Anakinra	C	Unknown	100 Milligram	Not Reported
	Ativan	C	Unknown	Unk	Not Reported
	Codeine	C	Unknown	Unk	Not Reported
	Darifenacin	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Dilaudid	C	Unknown		Not Reported
	Diphenhydramine	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Kadian	C	Unknown	Unk	Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk	Not Reported
	Loperamide	C	Unknown	Unk	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
	Omnaris	C	Unknown	Unk	Not Reported
	Oxyneo	C	Unknown		Not Reported
	Pantoprazole	C	Unknown		Not Reported
	Restasis	C	Unknown		Not Reported
	Rituximab	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Trimethoprim	C	Unknown		Not Reported
	Urispas	C	Unknown	200 Milligram	Not Reported
	Vagifem	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023859			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578006	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023868			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Abnormal; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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

Sulfasalazine	S	otherwise specified)		Not Reported
Naproxen	C	Unknown	500 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578076	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023929			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Prednisone			C	Unknown	30 Milligram, Qd		Not Reported
	Methotrexate			C	Oral	15 Milligram, Qwk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578415	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024447			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased;	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported

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

Pneumonia	Humira	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578458	EXPEDITED (15-DAY)		OT	US-JNJFOC-20200329683			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Gastric Disorder; Gastritis; Nail Discolouration; Nail Disorder; Nausea; Pancreatitis; Skin Lesion; Tuberculosis; Vomiting; Weight Decreased	Simponi Aria			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Spironolactone			C				Not Reported
	Verapamil			C				Not Reported
	Omeprazole			C				Not Reported
	Vitamin D /00107901/			C				Not Reported
	Calcium /00060701/			C				Not Reported
	Albuterol /00139501/			C				Not Reported
	Carafate			C				Not Reported
	Dulera			C				Not Reported
	Prednisone			C		5 Mg For The First 3 Days/ / - / / Tablets Taper Dose Down		Not Reported
	Ipratropium Bromide			C				Not Reported
	Albuterol Sulfate			C				Not Reported
	Singulair			C				Not Reported
	Claritin /00917501/			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578514	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020123955			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Enbrel			S	Unknown			Pfizer	
	Methotrexate Sodium			S	Unknown			Pfizer	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral	20 Mg, Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578942	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024664		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
	Hydroxychloroquine			S	Subcutaneous	400 Milligram, Qd		Not Reported	
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported	
	Methotrexate			S	Unknown	50 Milligram, Qwk		Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578947	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		51 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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BMS-2020-024594

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Tofacitinib			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578991	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024991			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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

Rituximab

S

Intravenous (not
otherwise specified)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17578997	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023964		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Spinal Column Injury; Surgical Failure; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown	15 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17579024	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024270			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram, Qwk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported

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

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulphate	S	Unknown	200 Milligram, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram	Not Reported
Synthroid	C	Unknown		Not Reported
Methotrexate	C	Unknown	Unk, Qwk	Not Reported
Meloxicam	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	12701613	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 1490		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral	2 In 1 Day		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Aleve	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Naproxen	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cosentyx	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Prednisone Acetate	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported

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

Folic Acid	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Hcq	C	Unknown	Not Reported
Acetaminophen And Codeine	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Insulin	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	12911486	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-048399			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Mirtazapine			S	Unknown	15 Milligram		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil S			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	13152994	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-004666		65 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
	Naproxen Sodium			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	14145032	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-095890			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Adverse Reaction; Drug Ineffective; Hospitalisation; Meningitis; Off Label Use	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported	
	Methotrexate			S	Intra-arterial	Unk		Not Reported	
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported	
	Actemra			S	Unknown	1 Dosage Form		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	14917725	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-071465			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Orencia			S	Unknown	577 Milligram		Bristol Myers Squibb	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			S	Unknown	577 Absent		Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	577 Milligram		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Unknown	577 Absent		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	577 Milligram		Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown	577 Milligram		Not Reported	
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Oral	Unk		Not Reported	

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

[Hydroxychloroquine Sulfate]					
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Simponi	S	Unknown	577 Milligram		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	Unk		Not Reported
Actemra	S	Unknown	577 Milligram		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk		Not Reported
Apo-Hydroxyquine	S	Unknown	Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Hydroxychloroquine Sulfate	S	Oral	577.0 Milligram		Not Reported
Hydroxychloroquine	S	Unknown	577 Absent		Not Reported
Desoximetasone	C	Oral	Unk		Not Reported
Cortisone	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	14921371	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-043739		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	40 Milligram		Not Reported
	Leflunomide			S	Unknown			Not Reported

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

Naproxen Sodium	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Xeljanz	S	Oral 5 Mg, Bid	Not Reported
Naproxen	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	15674968	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573976-00		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

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

Methotrexate	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	15949326	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-010949			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16073575	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 05670		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Infliximab			S	Unknown	Unknown		Not Reported

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

Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra	S	Unknown	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16125465	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091994			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported	
	Apo-Azathioprine			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	

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

	Humira	S	Subcutaneous	40 Milligram, Cyclical	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	Unk Unk, Q2wk	Not Reported
	Methotrexate Sodium	S	Oral	40 Mg (Titer), Q2wk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16248273	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2761854-00		48 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16439513	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2019-14998		8 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; C-Reactive Protein Increased;	Etanercept			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

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

Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab Adalimumab Adalimumab Humira Humira Enbrel Enbrel Enbrel Enbrel Leflunomide Methotrexate Methotrexate Orencia Orencia Plaquenil Rituximab Rituximab Rituximab Sulfasalazine Tocilizumab Tocilizumab Hydroxychloroquine Sulfate Actemra	S S S S S S S S S S S S S S S S S S S S S S S S S	otherwise specified) Intravenous (not otherwise specified) Subcutaneous Unknown Subcutaneous Subcutaneous Unknown Intravenous (not otherwise specified) Subcutaneous Subcutaneous Oral Subcutaneous Subcutaneous Unknown Unknown Unknown Unknown Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unknown Solution Subcutaneous Unknown	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16485230	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2835174-00			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Head Injury; Road Traffic Accident	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16740243	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA196426		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal; Bone Density Abnormal; Carpal Tunnel Syndrome; Condition Aggravated; Diarrhoea; Drug Ineffective; Fibromyalgia; Gait Disturbance; General Physical Health Deterioration; Hepatic Enzyme Increased; Joint Swelling; Liver Function Test Abnormal; Neuropathy Peripheral; Osteoarthritis; Osteopenia; Pain; Pain In Extremity; Poor Venous Access; Procedural Pain; Product Use In Unapproved Indication; Red Blood Cell Sedimentation Rate	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qw		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	1 Df, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	400 Mg, Qd		Not Reported

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

Abnormal; Rheumatoid Arthritis; Sleep Disorder; Spinal Stenosis; Treatment Failure	Plaquenil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Tramacet	S	Unknown		Not Reported
	Actonel	C	Unknown	35 Mg, Qw	Not Reported
	Calcium	C	Unknown		Not Reported
	Lorazepam	C	Unknown	1 Mg, Qd	Not Reported
	Lyrica	C	Oral	150 Mg, Bid	Not Reported
	Metformin	C	Unknown	5 Mg, Qd	Not Reported
	Metformin	C	Unknown	500 Mg, Bid	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk Unk, Qmo	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Subcutaneous	Unk	Not Reported
	Methylprednisolone Acetate	C	Intramuscular	40 Mg, Qmo	Not Reported
	Methylprednisolone Acetate	C	Unknown	Unk	Not Reported
	Nortriptyline	C	Unknown	Unk	Not Reported
	Nortriptyline	C			Not Reported
	Premarin	C	Unknown	0.625 Mg, Unk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Vagifem	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Nortriptyline Hydrochloride	C	Unknown	20 Mg, Qd	Not Reported
	Nortriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	35 Mg, Every Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	16740961	EXPEDITED (15-DAY)		HO, OT	DE-ROCHE-2386588			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Arthralgia; Arthralgia; Arthropathy; Atrial	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported

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

Fibrillation; Bronchitis; Ligament Sprain; Nasopharyngitis; Oedema	Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Peripheral; Pain In	Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Extremity; Paraesthesia;	Lyrica	S	Unknown	100 Mg, Tid (1 - 1 - 1)	Not Reported
Peripheral Coldness;	Sildenafil Citrate	S	Unknown	60 Milligram, Daily Dose	Not Reported
Pulmonary Hypertension;	Volibris	S	Oral	30 Milligram, Qd	Not Reported
Rheumatoid Arthritis;	Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Somnolence; Therapeutic	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
Product Effect Incomplete;	Spasmolyt	S	Unknown	30 Mg (0 - 0 - 1)	Not Reported
Visual Impairment	Spasmolyt	S	Unknown	15 (Unit Not Specified), Qd ((1 - 0 - 0))	Not Reported
	Omeprazole	S	Oral	1 Df, Bid (1 - 0 - 1)	Not Reported
	Ramipril	S	Oral	1 Df, Bid (1 - 0 - 1)	Not Reported
	Eliquis	S	Unknown	2.5 Mg Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17390605	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-006953		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Naproxen			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulphate			S	Unknown	400 Milligram		Not Reported	
	Xeljanz			S	Oral	5 Milligram(2 Every One Week)		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	

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

Naproxen Sodium	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Folic Acid	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17578578	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023106		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Unknown	500 Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Q2wk		Not Reported
	Leflunomide			S	Oral	20 Unk		Not Reported
	Methotrexate			S	Unknown	Unk, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17578721	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- 202003001831			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Cushingoid; Diarrhoea;	Hydroxychloroquine	S	Unknown	Unk	Concordia
Nausea; Nightmare; Renal	Arava	S	Oral	20 Mg, Qd	Not Reported
Pain; Sleep Terror;	Arava	S	Unknown	Unk	Not Reported
Therapeutic Response	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
Decreased; Treatment	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Failure; Weight Increased	Methotrexate	S	Oral	25 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Weekly	Not Reported
	Azathioprine	C			Not Reported
	Humira	C		Unk	Not Reported
	Leucovorin	C		Unk	Not Reported
	Prevnar 13	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17578725	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- GSH201703-001913			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Hydroxychloroquine Sulfate			S	Oral	Unknown, Tablet		Concordia
Arthropathy; Arthropathy;	(Authorized Generic),Plaquenil							
Condition Aggravated;	Hydroxychloroquine			S	Unknown	Unknown		Concordia
Condition Aggravated;	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
Contraindicated Product	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
Administered; Drug	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
Hypersensitivity; Drug	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
Ineffective; Finger	Sodium Aurothiomalate			S	Parenteral	Unknown		Not Reported
Deformity; Finger	Arava			S	Oral	Unk		Not Reported
Deformity; Limb	Actemra			S	Unknown	Unknown		Not Reported
Operation; Off Label Use;	Enbrel			S	Subcutaneous	Unknown		Not Reported
Pain; Peripheral Swelling;	Humira			S	Subcutaneous	Unknown		Not Reported
Peripheral Swelling; Rash;	Methotrexate			S	Unknown	Unknown		Not Reported
Swelling; Tendon	Methotrexate			S	Unknown	Unk		Not Reported
Disorder; Tendon	Orencia			S	Intravenous (not	Unknown		Not Reported
Operation; Tenosynovitis;					otherwise specified)			
Treatment Failure;								
Urticaria; Urticaria; Wrist								
Surgery								

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

Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rocuronium Bromide	S	Unknown	Unknown	Not Reported
Rocuronium Bromide	S	Unknown	Unk	Not Reported
Codeine	S	Unknown	Unknown	Not Reported
Gold	S	Unknown	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Unknown	Not Reported
Benzylpenicillin Sodium	S	Unknown	Unknown	Not Reported
Phenoxymethylpenicillin Potassium	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Prednisone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17578782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023426		72 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	640 Milligram, Q4wk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17578902	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568831		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17578910	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023485			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown	162 Milligram		Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	

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Azathioprine

C

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579095	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-202003001832			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
Abdominal Pain;	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
Diarrhoea; Diarrhoea;	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579314	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-000918			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree; Cardiac Failure;	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Ipca
Cardiomyopathy;	Furosemide			S	Intravenous (not otherwise specified)	Unk		Ipca
Cardiotoxicity; Renal Impairment	Prednisone			C	Unknown	Unk		Not Reported
	Mycophenolate			C	Unknown	Unk		Not Reported
	Rituximab			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579324	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1483			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea;	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Methotrexate (Trade Name Unknown)			S	Other			Not Reported

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Enbrel	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Celebrex	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579472	EXPEDITED (15-DAY)	OT		CA-ROCHE-2567801		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Rituxan			S	Intravenous drip			Not Reported
Blood Cholesterol	Apo-Azathioprine			S	Unknown			Not Reported
Increased;	Apo-Leflunomide			S	Unknown			Not Reported
Contraindicated Product	Arava			S	Unknown			Not Reported
Administered; Drug	Azathioprine			S	Unknown			Not Reported
Ineffective; Drug	Enbrel			S	Subcutaneous			Not Reported
Intolerance; Off Label Use;	Etanercept			S	Unknown			Not Reported
Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Parenteral			Not Reported

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Orencia	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

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25-Mar-2020	17579865	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1208924		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Levofloxacin			S	Oral	1000 Mg		Teva	
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	2 Dosage Forms		Not Reported	
	Ideos			S	Oral	2 Dosage Forms		Not Reported	
	Acarizax			S	Oral			Not Reported	
	Lutenyl			C				Not Reported	
	Cortancyl			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579885	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025463		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown			Bristol Myers Squibb	
	Azathioprine			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17580009	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020124022			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate Sodium			S		20 Mg, Weekly (Therapy Duration: 7 Years)		Pfizer	
	Enbrel			S		Unk (Therapy Duration: 9 Months)		Pfizer	
	Rituximab			S		Unk (Therapy Duration: 3 Years)		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk (1 Every 2 Weeks, Therapy Duration: 346 Days)		Not Reported	
	Hydroxychloroquine			S		200 Mg, 2x/Day (Therapy Duration: 9 Years)		Not Reported	
	Remicade			S		Unk (Therapy Duration: 2 Years)		Not Reported	
	Xeljanz			C		5 Mg, 2x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17580309	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-023667		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	

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	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581498	NON-EXPEDITED			US-PFIZER INC-2020122192		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Sulfasalazine			S		Unk		Pfizer	
	Actemra			S		Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581796	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025438			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown 12.5 Milligram, Bid	Not Reported
Arava	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581877	DIRECT		OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Abnormal Weight Gain; Alopecia; Chest Pain; Dizziness; Dyspnoea; Fatigue; Joint Swelling; Nausea; Photosensitivity Reaction; Syncope; Tremor	Hydroxychloroquine 200 Mg			S	Oral	Quantity:2 Tablet(S);	5 YR	Not Reported
	Prem-Pro 0.3mg/1.5mg			C				Not Reported
	Ventolin Inhaler			C				Not Reported
	Vit B (Complex)			C				Not Reported
	Vitamin C			C				Not Reported
	Vitamin D			C				Not Reported
	Zinc			C				Not Reported
	Calcium			C				Not Reported
	Magnesium			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Grape Seed Extract			C				Not Reported
	St Johns Wort			C				Not Reported
	Stainging Nettle			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581909	EXPEDITED (15-DAY)		DE, HO, LT, OT	NVSC2020CA083709			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Deep Vein Thrombosis;	Ilaris			S	Subcutaneous	Unk		Novartis
Diverticulitis; Drug	Ilaris			S	Unknown	Unk		Novartis
Ineffective; Joint Swelling; Off Label Use; Pain;	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
Pulmonary Embolism; Renal Failure	Rituximab			S	Unknown	Unk		Not Reported

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

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Actemra	S	Unknown	Unk	Not Reported
Actemra	S			Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Anakinra	S			Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S			Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Enbrel	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S			Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581930	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030615		44 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Marrow Failure; Drug Interaction	Methotrexate			S	Subcutaneous	10 Milligram, Qw		Not Reported	
	Dolquine			S	Oral	200 Milligram, Bid (12 Hours)		Mylan	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581934	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CA083373			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis	
	Ilaris			S	Subcutaneous	Unk		Novartis	
	Rituximab			S	Unknown	Unk		Not Reported	
	Rituximab			S				Not Reported	
	Methotrexate Sodium			S	Intra-arterial	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Oral	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S				Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S				Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S				Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Oxyquinoline Sulfate			S	Unknown	Unk		Not Reported	
	Oxyquinoline Sulfate			S				Not Reported	
	Remicade			S	Unknown	Unk		Not Reported	

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

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581956	EXPEDITED (15-DAY)	HO, LT, OT		NVSC2020CA083719		57 YR	Male	CAN

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

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

	Humira	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581969	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1030618		30 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Mycophenolate Mofetil			S	Oral	500 Milligram, Bid		Not Reported	
	Dolquine			S	Oral	200 Milligram, Bid		Mylan	
	Rituximab			C	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17583060	EXPEDITED (15-DAY)		DS	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025465		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Fine Motor Skill	Orencia			S	Intravenous (not			Bristol Myers Squibb	

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

Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Anakinra	S	otherwise specified)	Unknown	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous drip		Not Reported
	Humira	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17583075	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025482			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Fissure; Bronchitis; Diarrhoea; Drug Ineffective; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous	25 Milligram, Qd		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17583096	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025534			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17583157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025394			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	12889782	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013285		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex

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Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture	Apo-Leflunomide	S	Oral	5 Mg, Q.12h	Apotex
Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use;	Apo-Leflunomide	S	Unknown	Unk Unk, Bid	Apotex
Osteoporosis;	Apo-Naproxen	S	Unknown	Unk	Apotex
Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Q.12h	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Humira	C	Subcutaneous	Unk	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	12914312	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091576		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction;	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Arthralgia; Cardiovascular Disorder; Drug	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported	
Hypersensitivity; Drug	Adalimumab			S	Unknown	Unk		Not Reported	
Ineffective; Inflammation;	Cimzia			S	Subcutaneous	Unk		Not Reported	
Joint Swelling; Muscle	Enbrel			S	Unknown	Unk		Not Reported	
Spasms; Off Label Use;	Gold			S	Unknown	Unk, Qd		Not Reported	
Red Blood Cell									

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

Sedimentation Rate Increased; Urticaria	Gold	S	Unknown	Unk, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Parenteral	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram, Qwk	Not Reported
	Infliximab	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Subcutaneous	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	6 Milligram, Bid	Not Reported

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

Actemra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	6 Milligram, Qd	Not Reported
D-Penicillamine	C	Unknown	Unk	Not Reported
Phenylbutazone	C	Unknown		Not Reported
Methotrexate	C	Parenteral	25 Milligram, Q4wk	Not Reported
Humira	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	13057420	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1869749		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	13057569	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015705		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported	
	Etanercept			S	Unknown	Unk		Not Reported	
	Advil /00109201/			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	Ketorolac			C	Unknown	Unk		Not Reported	
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported	
	Naproxen			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	13059083	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015740		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Joint Swelling; Pain; Shoulder Operation; Therapeutic Response Decreased	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Enbrel			S	Unknown	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	

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

Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	13180365	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA012856		60 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	13968018	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2017AP017267		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Gastrooesophageal Reflux Disease; Hepatic Enzyme	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
	Apo-Hydroxyquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex

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

Increased; Hypokinesia; Joint Range Of Motion Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Delayed	Leflunomide Methotrexate Methotrexate Arava Enbrel Humira Methotrexate Sodium Orencia Remicade Xeljanz Sulfasalazine Plaquenil /00072602/ Cortisone Prednisone Tylenol Arthritis Naprosyn /00256201/ Rabeprazole	S S S S S S S S S S S S S C C C C C	Unknown Unknown Unknown Unknown Subcutaneous Subcutaneous Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Oral Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk 25 Mg, Q.Wk. Unk 20 Mg, Qd 50 Mg, Q.Wk. 40 Mg, Unk 25 Mg, Q.Wk. 500 Mg, Unk 200 Mg, Unk 5 Mg, Bid Unk 200 Mg, Unk Unk 5 Mg, Qd Unk Unk Unk	Apotex Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	14692979	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018CA055436		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C- Reactive Protein	Ilaris			S	Subcutaneous	Unk		Novartis	
Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug	Ilaris			S	Intravenous (not otherwise specified)	Unk		Novartis	
	Ilaris			S	Unknown	Unk		Novartis	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Intra-arterial	Unk		Not Reported	

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

Hypersensitivity; Drug	Leflunomide	S	Oral		Not Reported
Ineffective; Drug	Leflunomide	S	Unknown	Unk	Not Reported
Intolerance; Feeling	Apo-Leflunomide	S	Unknown	Unk	Not Reported
Abnormal; Haemoglobin	Apo-Leflunomide	S			Not Reported
Decreased; Herpes	Gold	S	Unknown	Unk	Not Reported
Zoster; Intentional Product	Actemra	S	Unknown	Unk	Not Reported
Use Issue; Interstitial Lung	Actemra	S	Unknown	Unk	Not Reported
Disease; Intestinal Sepsis;	Anakinra	S	Unknown	Unk	Not Reported
Joint Swelling; Myocardial	Anakinra	S	Unknown	Unk	Not Reported
Infarction; Off Label Use;	Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported
Pain; Photosensitivity	Sulfasalazin	S			Not Reported
Reaction; Pulmonary	Enbrel	S	Subcutaneous	Unk	Not Reported
Embolism; Pulmonary	Enbrel	S	Unknown	Unk	Not Reported
Thrombosis; Red Blood	Humira	S	Subcutaneous	Unk	Not Reported
Cell Sedimentation Rate	Humira	S			Not Reported
Increased; Renal Failure;	Hydroxychloroquine	S	Unknown	Unk	Not Reported
Sepsis; Stomatitis;	Hydroxychloroquine	S	Oral	Unk	Not Reported
Terminal State;	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Thrombosis; Urticaria	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Unknown	400 Mg	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported

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

Marijuana	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
Xeljanz	C	Oral	2 Df, Qd	Not Reported
Xeljanz	C	Unknown	5 Mg	Not Reported
Rituximab	C	Unknown		Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown		Not Reported
Prednisone	C	Unknown	1 Df, Qd	Not Reported
Urelumab	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	15042955	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021658		54 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Etanercept			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

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

	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	15411090	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186044		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	15635401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105895			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	50 Mg, Qwk		Not Reported

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

Therapeutic Response Decreased	Hydroxychloroquine	S	Unknown	200.0 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25.0 Mg, Qwk	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qwk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Gold Sodium Thiomalate	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	15680306	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2575130-00		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rocuronium			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Plaquenil			S	Oral			Not Reported	

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

Rocuronium Bromide	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	15867265	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190123564		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; C-Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Simponi Iv			S	Intravenous (not otherwise specified)			Not Reported
	Simponi Iv			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	15946323	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-010990		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb

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

Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Arava	C	Unknown		Not Reported
	Codein	C	Unknown		Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C	Oral		Not Reported
	Acetaminophen	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16125329	EXPEDITED (15-DAY)		OT	PHHY2019CA064258		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Ciclosporin			S	Subcutaneous			Novartis
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported

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

Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Rituxan	S	Intravenous drip	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Xeljanz	C	Unknown	Unk, Qd	Not Reported
Xeljanz	C	Oral	10 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16128012	EXPEDITED (15-DAY)		OT	PHHY2019CA064350		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral	S	Subcutaneous	Unk	Novartis
	Neoral	S	Oral	Unk	Novartis
	Ciclosporin	S	Subcutaneous	Unk	Novartis
	Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16480411	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-		60 YR	Female	CAN

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

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16536778	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071381			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Contraindicated Product	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Clindamycin			S	Unknown			Actavis

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

Administered; Cough;	Codeine	S	Unknown	Not Reported
Diarrhoea; Drug	Enalapril	S	Unknown	Teva
Hypersensitivity; Drug	Hctz	S	Unknown	Ivax
Ineffective; Dyspnoea;	Losartan	S	Unknown	Teva
Gastric Disorder; Hepatic	Methotrexate	S	Unknown	Barr
Steatosis; Hypertension;	Methotrexate	S	Subcutaneous	Barr
Loss Of Employment;	Methotrexate	S	Subcutaneous	Barr
Malaise; Nausea; Rash;	Metoprolol Tartrate	S	Unknown	Not Reported
Therapeutic Product Effect	Moxifloxacin Hydrochloride	S	Unknown	Teva
Decreased	Moxifloxacin Hydrochloride	S	Unknown	Teva
	Pantoprazole Magnesium	S	Unknown	Teva
	Penicillin G	S	Unknown	Teva
	Cefalexin	S	Unknown	Not Reported
	Enalapril Maleate	S	Unknown	Teva
	Losartan	S	Unknown	Teva
	Arava	S	Unknown	Not Reported
	Biaxin	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Levaquin	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Diazide (Gliclazide)	S	Unknown	Not Reported
	Lopressor	S	Unknown	Not Reported

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

Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	100 Milligram Daily;	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Isoniazid	S	Unknown		Not Reported
Cipro	S	Unknown		Not Reported
Penicillin Nos	S	Unknown		Not Reported
Esomeprazole	C	Unknown		Not Reported
Gold	C			Not Reported
Hydroxychloroquine	C			Not Reported
Iron Sucrose	C	Unknown		Not Reported
Prednisone	C	Unknown	8.5 Milligram Daily;	Not Reported
Colchicine	C			Not Reported
Coversyl [Perindoprilrbumine]	C			Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C			Not Reported
Levothyroxine Sodium	C			Not Reported
Ranitidine	C			Not Reported
Venofer	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16767573	EXPEDITED (15-DAY)		OT	PHHY2018CA068442		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Oral	Unk		Novartis
	Ciclosporin			S	Unknown			Novartis
	Adalimumab			S	Subcutaneous	40 Mg, Biw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Biw		Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Apo Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Oral	Unk	Not Reported
Apo Leflunomida	S	Unknown		Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Enbrel	S	Unknown	50 Mg, Biw	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg, Qw	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Qw	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Orencia	S	Unknown	75 Mg, Qw	Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown	40 Mg, Biw	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported

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

	Risedronate	C	Oral	35 Mg, Qw	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)		Not Reported
	Arava	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16792405	EXPEDITED (15-DAY)		HO	JP-GLAXOSMITHKLINE-JP2019JPN160709		50 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Focal Segmental Glomerulosclerosis	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Benlysta			S	Subcutaneous	200 Mg		Glaxosmithkline
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Predonine			C		Unk		Not Reported
	Mycophenolate Mofetil Capsule			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16982578	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20191009548		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug	Otezla			S	Unknown	60 Milligram		Celgene
	Otezla			S	Unknown			Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported



Detailed Report

Intolerance; Enthesopathy;	Enbrel	S	Unknown		Not Reported
Erythema; Granuloma	Humira	S	Subcutaneous	40 Milligram	Not Reported
Skin; Headache;	Humira	S	Unknown		Not Reported
Hypercalcaemia;	Apo-Hydroxyquine	S	Unknown		Not Reported
Inflammation; Infusion	Apo-Ibuprofen	S	Oral		Not Reported
Related Reaction; Loss Of Personal Independence In	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
Daily Activities; Nausea;	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
Panniculitis; Peripheral	Infliximab	S	Oral		Not Reported
Swelling; Psoriatic	Infliximab	S			Not Reported
Arthropathy; Rash; Rash	Methotrexate	S	Unknown	1.7143 Milligram	Not Reported
Pruritic; Red Blood Cell	Methotrexate	S	Unknown	1.7857 Milligram	Not Reported
Sedimentation Rate; Red	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
Blood Cell Sedimentation	Methotrexate	S	Subcutaneous	2.5 Milligram	Not Reported
Rate Increased;	Methotrexate	S	Unknown	1.4286 Milligram	Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Subcutaneous		Not Reported
Rheumatoid Nodule; Skin	Methotrexate	S	Unknown	7.1429 Milligram	Not Reported
Necrosis; Skin Ulcer;	Methotrexate	S	Unknown	5.7143 Milligram	Not Reported
Synovitis; Tendonitis;	Methotrexate	S	Unknown	6.8571 Milligram	Not Reported
Tenosynovitis; Tongue	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Disorder; Ulcer	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported

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

Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown	1000 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16988122	EXPEDITED (15-DAY)		OT	CA-SA-2019SA298961			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Abnormal	Cefixime			S	Unknown	Unk		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine Salt Not Specified			S				Not Reported
	Nifedipine			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown			Sanofi
	Zopiclone			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Oral	100 Mg		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg Q0, 2, 6, 8 Weeks		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17455140	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202002000974			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Maternal Exposure During Pregnancy; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S		Unk		Concordia
	Azathioprine			S		50 Mg, Qd		Not Reported
	Azathioprine			S		Retreatment With Low-Dose 50 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S		Moderate Doses Of		Not Reported

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

Prednisone	S	Prednisone 2.5 Mg, Qd	Not Reported
Belimumab	S	Unk	Not Reported
Belimumab	S	10 Mg/Kg, Monthly	Not Reported
Belimumab	S	Unk, Resumed 2 Weeks After Delivery	Not Reported
Mycophenolate	C	Unk	Not Reported
Mycophenolate	C	Switching Back	Not Reported
Mycophenolate	C	Continued During The Initial 6 Months Of Belimumab Infusions And Then Tapered Off	Not Reported
Warfarin	C	Unk	Not Reported
Warfarin	C	Resumed Warfarin	Not Reported
Low-Molecular-Weight Heparin	C	Unk	Not Reported
Enoxaparin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17533248	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200309558		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Stelara			S	Subcutaneous			Not Reported
Adverse Drug Reaction;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Drug Ineffective;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Dyspepsia; General Physical Health	Simponi			S	Subcutaneous			Not Reported
Deterioration; Nausea; Off Label Use; Product Use In Unapproved Indication;	Simponi			S	Subcutaneous			Not Reported
Psoriatic Arthropathy;	Cimzia			S	Subcutaneous			Not Reported
Rheumatoid Arthritis;	Cosentyx			S	Unknown			Not Reported
Sleep Disorder; Uveitis	Enbrel			S	Unknown			Not Reported

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

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Otezla	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Myochrysine	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Unknown	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sirukumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Actemra	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583205	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024031		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Condition	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
Aggravated; Drug Ineffective; Drug	Actemra			S	Unknown	Unk		Not Reported
Intolerance; Fatigue; Glossodynia; Hand	Apo-Prednisone			S	Unknown	5 Milligram		Not Reported
Deformity; Pain; Pemphigus; Swelling;	Arava			S	Unknown	Unk		Not Reported
Systemic Lupus	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported

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

Erythematousus	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Q12h	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583207	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025557		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pulmonary Fibrosis	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583283	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB- 000888			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Ipca	
	Warfarin Sodium			S	Unknown	Unk		Ipca	
	Clopidogrel			S	Unknown	Unk		Not Reported	
	Atorvastatin			S	Unknown	Unk		Not Reported	
	Apixaban			S	Unknown	Unk		Not Reported	

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Rivaroxaban	S	Unknown	Unk	Not Reported
Low Molecular Weight Heparin	C	Unknown	Unk	Not Reported
Isoniazid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583491	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568766			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Subcutaneous			Not Reported
	Diclofenac			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2569483		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cimzia	S	Subcutaneous	Single Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Arava	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tylenol	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583521	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023661		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthralgia; Drug Ineffective;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
Hypersensitivity; Joint Swelling; Maternal Exposure During Pregnancy;	Actemra			S	Unknown	Unk		Not Reported	
Musculoskeletal Stiffness;	Alendronate Sodium			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	

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Pain; Pemphigus;	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Pericarditis; Product Use	Cetirizine Hydrochloride And	S	Unknown	Unk	Not Reported
Issue; Rheumatoid	Pseudoephedrine Hydrochloride				
Arthritis; Systemic Lupus	Cimzia	S	Subcutaneous	400 Milligram	Not Reported
Erythematosis;	Cortisone Acetate	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Desoximetasone	S	Oral	Unk	Not Reported
Decreased; Treatment	Enbrel	S	Subcutaneous		Not Reported
Failure	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Phosphate]				
	Plaquenil [Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Phosphate]				
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	40 Milligram	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported
			otherwise specified)		
	Rituxan	S	Intravenous (not	Unk	Not Reported
			otherwise specified)		
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Q12h	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Diclofenac	C	Unknown	50 Milligram	Not Reported

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Salazopyrin			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583547	EXPEDITED (15-DAY)	OT		CA-ROCHE-2571158			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Folic Acid			C				Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583562	EXPEDITED (15-DAY)	OT		CA-ORION CORPORATION ORION PHARMA-TREX2020-1479		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583564	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1490			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583582	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1504			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain; Psoriatic Arthropathy; Swelling; Therapeutic Product Effect Incomplete	Methotrexate (Trade Name Unknown)			S	Unknown				Not Reported
	Cosentyx			S	Unknown				Not Reported
	Hydroxychloroquine			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583834	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- 202003001844			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Neutropenia; Rash	Hydroxychloroquine			S	Unknown	200 Mg, Bid			Concordia
	Hydroxychloroquine			S	Unknown	Unk			Concordia
	Arava			S	Unknown	10 Mg, Qd			Not Reported
	Arava			S	Unknown	20 Mg, Qd			Not Reported
	Salazopyrin			C		Unk			Not Reported
	Solganal			C		Unk			Not Reported
	Methotrexate			C		Unk			Not Reported

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Codeine	C	Unk	Not Reported
Flurbiprofen	C	Unk	Not Reported
Cortisone	C	Intra-articular	Unk
Tylenol	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Gold	C	Unk	Not Reported
Prevacid	C	Unk	Not Reported
Penicillamine	C	Unk	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523564		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Diastolic Abnormal; Bone Marrow Toxicity; C-Reactive Protein Increased; Intentional Product Use Issue; Neuropathy Peripheral; Off Label Use; Paraesthesia; Rash; Thrombocytopenia	Rituxan			S	Intravenous (not otherwise specified)	1 Every Week For 4 Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Lyrica			C				Not Reported
	Synthroid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583878	NON-EXPEDITED		DE	NVSC2020US084343		30 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Malignant Melanoma	Dabrafenib	S	Unknown	150 Mg, Bid	Novartis
Stage Iv; Malignant	Dabrafenib	S			Novartis
Neoplasm Progression	Trametinib	S	Unknown	2 Mg, Qd	Not Reported
	Trametinib	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk, 400 To 600 Mg, Bid	Not Reported
	Hydroxychloroquine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583912	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567774		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Swelling; Candida Infection; Condition Aggravated;	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug Interaction; Joint Swelling;	Apo-Leflunomide			S	Oral			Not Reported
Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Apo-Prednisone			S	Unknown			Not Reported
Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased;	Arava			S	Unknown			Not Reported
Thyroid Neoplasm; Toxicity To Various Agents	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583952	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568809			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased;	Rituximab			S	Unknown			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584003	EXPEDITED (15-DAY)		HO	CA-ROCHE-2571253			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584031	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-241562		29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cellulitis; Drug Resistance;	Triamcinolone			S		Unk		Ranbaxy

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Gastrointestinal Disorder;	Tacrolimus	S	Topical	Unk	Not Reported
Pseudomonal Skin	Hydroxychloroquine	S	Unknown	Unk	Sun
Infection; Therapeutic	Clobetasol	S	Topical	Unk	Taro
Product Effect Incomplete;	Pentoxifylline	S	Unknown	Unk	Not Reported
Treatment Failure	Adalimumab	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584210	EXPEDITED (15-DAY)		OT	NVSC2020CA083918		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Remicade			S	Unknown	3 Mg (Powder For Solution)		Not Reported
	Orencia			S	Subcutaneous	125 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Unk (Solution)		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584216	EXPEDITED (15-DAY)		OT	NVSC2020CA082940		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral	S	Oral	Unk	Novartis
	Neoral	S	Subcutaneous	Unk	Novartis
	Cyclosporine	S	Unknown	Unk	Novartis
	Adalimumab	S	Subcutaneous	40 Mg, Unknown	Not Reported
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Unknown	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Qd	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unknown	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Xeljanz	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Sulfasalazine	S	Oral	1 Df, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown	Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	75 Mg, Qmo	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Oral	2000 Mg, Bid	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	40 Mg, Q2w	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported

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

		otherwise specified)		
Arava	C	Oral	1 Df, Qd	Not Reported
Cimzia	C	Subcutaneous	1 Df, Q2w	Not Reported
Risedronate	C	Oral	1 Df, Qw	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584497	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020125866			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure	Enbrel			S	Unknown			Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584625	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127462		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Infection; Leukopenia; Neutropenia	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584658	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020127350			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Sulfasalazine			S	Unknown	Unk		Pfizer	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584988	EXPEDITED (15-DAY)		OT	GB-TORRENT-00023236		29 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Apixaban			S	Unknown	Unknown		Unknown	
	Warfarin			S	Unknown	Unknown		Unknown	
	Rivaroxaban			S	Unknown	Unknown		Unknown	
	Clopidogrel			S	Unknown	Unknown		Not Reported	
	Hydroxychloroquine			S	Unknown	Unknown		Unknown	
	Atorvastatin			S	Unknown	Unknown		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585091	EXPEDITED (15-DAY)		OT	CA-ROCHE-2568730			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	

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Arthritis; Tuberculin Test Positive	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous	Solution	Not Reported
	Minocycline	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Amoxicillin Trihydrate; Clavulanate Potassium	C	Unknown		Not Reported
	Amoxil [Amoxicillin]	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570007			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Eczema; Sepsis; Urinary Tract Infection	Actemra			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Cbd Oil			C				Not Reported
	Dronabinol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585240	EXPEDITED (15-DAY)		OT	NVSC2020CA083916		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment	Methotrexate			S	Subcutaneous	20 Mg, Unknown		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

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

Failure	Neoral	S	Oral	Unk	Novartis
	Rituximab	S	Endocervical	Unk	Not Reported
	Cyclosporine	S	Unknown	Unk	Novartis
	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk (Solution)	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20 Mg, Unknown	Not Reported
	Orencia	S	Subcutaneous	125 Mg, Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unknown	Not Reported
	Simponi	S	Subcutaneous	Unk (Solution)	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Xeljanz	C	Unknown	5 Mg, Qd 2 Every 1 Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585302	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075362		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth	Hydroxychloroquine Sulfate			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Arava			S	Oral			Sanofi
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous	Unk, 1x		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

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Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiosulfate	C		Not Reported
	Methotrexate	C	Subcutaneous 25 Mg, Qw	Not Reported
	Prednisone	C	Intravenous (not otherwise specified) Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585303	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075074		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein	Hydroxychloroquine Sulfate			S				Sanofi
Abnormal; Diverticulitis;	Leflunomide			S				Sanofi
Drug Ineffective; Drug	Methotrexate			S				Not Reported
Intolerance; Joint Swelling;	Sulfasalazine			S				Not Reported
Rheumatoid Factor	Tofacitinib Citrate			S				Not Reported
Positive; X-Ray Abnormal	Actemra			S				Not Reported
	Diovan			C				Not Reported
	Docosahexanoic			C				Not Reported
	Acid;Eicosapentaenoic Acid							
	Sertraline			C				Not Reported
	Valtrex			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585304	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075084		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Arthralgia;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
Chronic Sinusitis;	Methotrexate			S	Unknown			Not Reported
Diverticulum; Drug	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
Ineffective;	Arava			S	Unknown			Sanofi
Haemochromatosis;	Actemra			S	Unknown			Not Reported
Impaired Work Ability;	Rituximab			S	Intravenous (not			Not Reported
Irritable Bowel Syndrome;								
Joint Swelling; Nausea;								
Osteoporosis; Treatment								

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Failure		Xeljanz		S	otherwise specified)		Oral	5 Mg, Bid	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
26-Mar-2020	17585306	EXPEDITED (15-DAY)		OT	CA-SA-2020SA074997			Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Colitis Microscopic; Gastrointestinal Disorder; Rash	Plaquenil			S		Unk G		Sanofi		
	Leflunomide			S		20 Mg		Sanofi		
	Methotrexate			C	Subcutaneous	25 Mg, Qw		Not Reported		
	Sulfasalazine			C		2 G		Not Reported		
	Venlafaxine Hydrochloride			C		Unk		Not Reported		
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
26-Mar-2020	17585763	EXPEDITED (15-DAY)		OT	NVSC2020CA083797		51 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous	Unk		Novartis		
	Neoral			S	Subcutaneous	Unk		Novartis		
	Cyclosporine			S	Unknown	Unk		Novartis		
	Methotrexate			S	Oral	20 Mg		Not Reported		
	Methotrexate			S	Subcutaneous	Unk		Not Reported		
	Apo-Leflunomide			S	Unknown	Unk		Not Reported		
	Actemra			S	Intravenous drip	8 Mg/Kg, Unk		Not Reported		
	Actemra			S	Intravenous drip	8 Mg/Kg, Unk		Not Reported		
	Enbrel			S	Subcutaneous	500 Mg (Every 1 Weeks)		Not Reported		
	Orencia			S	Subcutaneous	125 Mg		Not Reported		
	Plaquenil			S	Oral	Unk		Not Reported		
	Plaquenil			S	Subcutaneous	Unk		Not Reported		

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	Remicade		S	Intravenous drip	3 Mg/Kg,Unk			Not Reported	
	Xeljanz		C	Oral	5 Mg (2 Every 1 Day)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585786	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031634		29 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Infarction; Cerebrovascular Accident; Transient Ischaemic Attack; Treatment Failure	Atorvastatin			S	Unknown	Unk		Not Reported	
	Clopidogrel			S	Unknown	Unk		Not Reported	
	Warfarin			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585836	EXPEDITED (15-DAY)		OT	NVSC2020CA083902			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Subcutaneous	20 Mg, (16 Years)		Not Reported	
	Neoral			S	Oral	20 Mg (16 Years)		Novartis	
	Enbrel			S	Subcutaneous	50 Mg (3 Months)		Not Reported	
	Plaquenil			S	Oral	20 Mg (16 Years)		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	3.0 Mg/Kg (12 Years)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17585895	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025893		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Injury; Drug Ineffective; Fall	Orencia			S	Unknown			Bristol Myers Squibb	
	Arava			S	Unknown	20 Milligram		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	

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	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	25 Milligram	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17586685	NON-EXPEDITED		DE	NVSC2020US084340		59 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malignant Melanoma Stage Iv; Malignant Neoplasm Progression	Dabrafenib			S	Oral	150 Mg, Bid		Novartis
	Dabrafenib			S				Novartis
	Trametinib			S	Oral	2 Mg, Qd		Not Reported
	Trametinib			S				Not Reported
	Hydroxychloroquine			S	Oral	400- 600 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	600 Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17586974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025902			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

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

Sulfasalazine	S	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587086	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024299		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	20 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram, Qd		Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Risedronate			S	Oral	35 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587200	EXPEDITED (15-DAY)		DS, HO, OT	CA-PFIZER INC-2018488256		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Product Use In Unapproved Indication; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Enbrel			S	Subcutaneous	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Milligram, Unk		Pfizer
	Sulfasalazine			S	Unknown	Unk		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo Hydroxyquine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Prednisone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587396	EXPEDITED (15-DAY)		OT	NVSC2020CA066714		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Cyclosporine			S	Subcutaneous	Unk		Novartis

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

Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Humira	S	Subcutaneous		Not Reported
Plaquenil	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz Xr	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587547	EXPEDITED (15-DAY)		OT	NVSC2020CA084494		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Neoral			S	Subcutaneous			Novartis
	Neoral			S	Unknown	Unk		Novartis
	Cyclosporine			S	Unknown			Novartis
	Leflunomide			S	Unknown	20.0 Mg, Qd		Not Reported
	Leflunomide			S				Not Reported
	Methotrexate Sodium			S	Subcutaneous	20.0 Mg		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

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

Sulfasalazine	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3.0 Mg	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Cimzia	C	Subcutaneous	200.0 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587578	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1031637		50 YR	Female	GBR

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587783	NON-EXPEDITED			NVSC2020US083346			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Drug Ineffective	Xolair	S	Unknown	Unk, Q4w	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Novartis
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Hydroxyzine	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Dupilumab	S	Unknown	Unk	Not Reported
	Dapsone	S	Unknown	Unk	Not Reported
	Lycor	S	Unknown		Not Reported
	Singulair	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	C	Unknown	1 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17588061	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020126107			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown			Pfizer
	Enbrel			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17588436	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025383		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia Apo-Azathioprine Arava Enbrel Humira Hydroxychloroquine Methotrexate Rituximab Sulfasalazine Xeljanz Methotrexate	S S S S S S S S S S S S	Subcutaneous Unknown Unknown Subcutaneous Subcutaneous Unknown Oral Intravenous drip Unknown Unknown Unknown Subcutaneous	750 Milligram 50 Milligram 40 Milligram 2000 Milligram 	Bristol Myers Squibb Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17588455	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025435			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosis	Orencia			S	Subcutaneous			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown 500 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17588457	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025454			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine Sulphate			S	Oral	400 Milligram		Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17588491	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026044		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus Inadequate Control; Drug Hypersensitivity; Drug	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported	
	Asacol			S	Unknown	800 Mg 3 Every 2 Days		Not Reported	
	Diamicron			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

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Detailed Report

Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Increased	Enbrel	S	Subcutaneous	50 Milligram	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous drip	1000 Milligram	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Diphenhydramine	C	Oral	50 Milligram	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Methylprednisolone Acetate	C	Intra-articular	Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17591609	DIRECT	Y	LT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Haemodialysis; Intensive Care	Plaquenil			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	11480152	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150902732			Female	CAN

FDA Adverse Event Reporting System

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy;	Simponi			S	Subcutaneous			Not Reported	
Back Pain; C-Reactive	Xeljanz			S	Oral			Not Reported	
Protein Abnormal;	Plaquenil /00072602/			S	Oral			Not Reported	
Cataract; Cerebrovascular	Humira			S	Subcutaneous			Not Reported	
Accident; Crying;	Enbrel			S	Subcutaneous			Not Reported	
Deformity; Depression;	Senokot			C	Unknown			Not Reported	
Disability; Drug Ineffective;	Coversyl			C	Unknown			Not Reported	
Dry Eye; Dyspnoea;	Percocet			C	Unknown			Not Reported	
Fatigue; Fine Motor Skill	Ativan			C	Sublingual	Night At Bedtime		Not Reported	
Dysfunction; Foot	Lovastatin			C	Unknown			Not Reported	
Deformity; Gait	Flexeril			C	Oral			Not Reported	
Disturbance; Hand	Flexeril			C	Oral			Not Reported	
Deformity; Hepatic	Cyclobenzaprine Hydrochloride			C	Subcutaneous			Not Reported	
Enzyme Increased;	Acetaminophen W/Oxycodone			C				Not Reported	
Hepatitis C; Hypokinesia;	Hydrochloride								
Impaired Healing;									
Insomnia; Joint Swelling;									
Loss Of Personal									
Independence In Daily									
Activities; Muscle Atrophy;									
Muscle Spasms;									
Musculoskeletal Disorder;									
Musculoskeletal Pain;									
Myalgia; Papule;									
Peripheral Swelling;									
Procedural Pain; Red									
Blood Cell Sedimentation									
Rate Abnormal;									
Rheumatoid Arthritis;									
Rheumatoid Arthritis;									
Rheumatoid Nodule;									
Shoulder Deformity;									
Surgical Failure; Swelling;									
Weight Decreased; Wrist									
Deformity									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	12883751	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013303		53 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Apo-Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Unk		Not Reported
	Methotrexate Sodium			S	Unknown	15 Unk, Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Plaquenil /00072602/			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	12893895	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150810477		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Nasopharyngitis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

Hydroxychloroquine Sulfate	S		Not Reported
Lyrica	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Acetaminophen	C		Not Reported
Arava	C		Not Reported
Codeine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	13059056	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015753		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Leflunomide			S		20 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported

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

Celebrex	S	Unknown	Unk	Not Reported
Celebrex	S			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	2.5 Mg, Unk	Not Reported
Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	13244457	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006744			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	1 G, Qd		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	13519394	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038533		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abdominal Pain; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Orencia	S	Subcutaneous	150 Mg, Qmo	Bristol Myers Squibb
	Sulfasalasin	S	Unknown	500 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Qd	Not Reported
	Celebrex	S	Unknown	200 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naprosyn [Naproxen]	S	Unknown	500 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	14628698	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-037929		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	1 Df, Qwk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Methotrexate Sodium			S	Oral	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported	

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

Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
Xeljanz	S	Oral	5 Milligram, Every One Day	Not Reported
Xeljanz	S	Oral	5 Milligram, Q2wk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Lyrica	S	Oral	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Prednisone	C	Oral	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, Q2wk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	15049818	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP015756		41 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Leflunomide			S	Oral			Apotex	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	15076377	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP016010			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex	
	Enbrel			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	25 Mg, Q.Wk.		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported	
	Rituxan			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	15400431	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-083976		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb	
	Metformin Hydrochloride			S	Unknown	500 Mg, Bid		Bristol Myers Squibb	
	Desoximetasone			S	Unknown			Not Reported	
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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

Altace	C	Unknown	5 Mg, Qd	Not Reported
Asa	C	Unknown	81 Mg, Qd	Not Reported
Folic Acid	C	Unknown	1 Df, Unk	Not Reported
Methotrexate	C	Oral	15 Mg, Qd	Not Reported
Omega 3 [Fish Oil;Tocopherol]	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Unknown	20 Mg, Qd	Not Reported
Rosuvastatin Calcium	C	Unknown		Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	15899841	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019048311		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Coronavirus Infection; Drug Ineffective; Immunodeficiency; Nasal Congestion; Pain	Flector			S	Transdermal	1 Patch To Skin, Twice A Day		Pfizer
	Flector			S	Oral			Pfizer
	Diclofenac Sodium			S		Unk		Not Reported
	Oxymorphone			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Pennsaid			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Cbd			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	15978351	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-013839		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Orencia	S	Unknown		Bristol Myers Squibb
	Celebrex	S	Oral	200 Milligram, Q12h	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Q12h	Not Reported
	Arava	C	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Oral	5 Milligram, Q12h	Not Reported
	Rituximab	S	Intravenous drip		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	16108792	EXPEDITED (15-DAY)		HO, LT	PHHY2019CA062642			Male	CAN

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

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	Apo-Leflunomide	S				Not Reported
	Enbrel	S	Unknown	Unk		Not Reported
	Enbrel	S	Subcutaneous	Unk		Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Humira	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia	S	Unknown	Unk		Not Reported
	Remicade	S	Unknown	Unk		Not Reported
	Remicade	S				Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine	S				Not Reported
	Hydroxychloroquine	S	Unknown	Unk		Not Reported
	Hydroxychloroquine	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	16889106	EXPEDITED (15-DAY)		OT	CA-SA-2019SA271272			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17064857	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190827902		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastritis; Headache; Nausea; Pain; Platelet Count Increased; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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Plaquenil /00072602/

S

Oral

Dose Doubled In Jan-2020

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17335679	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-HORIZON-PRE-0036-2020			Female	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Prednisone			S	Transplacental	Unk		Not Reported
	Omeprazole			S		Unk		Not Reported
	Bisulepin			S	Transplacental	Unk		Not Reported
	Aminomethylbenzoic Acid			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Vitamin D [Colecalciferol]			S	Transplacental	Unk		Not Reported
	Folic Acid			S	Transplacental	Unk		Not Reported
	Cefixime			S	Transplacental	Unk		Not Reported
	Paracetamol			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Privigen			S	Transplacental	Unk		Not Reported
	Ornidazole			S	Transplacental	Unk		Not Reported
	Magnesium Lactate			S	Transplacental	Unk		Not Reported
	Vitamin K Nos			S	Transplacental	Unk		Not Reported
	Bisoprolol Fumarate			S	Transplacental	Unk		Not Reported
	Vulmizolin			S	Transplacental	Unk		Not Reported
	Vitamin B Complex			S		Unk		Not Reported
	Calcium Carbonate			S	Transplacental	Unk		Not Reported
Potassium Chloride			S	Transplacental	Unk		Not Reported	
Fluconazole			S	Transplacental	Unk		Not Reported	
Penicillin G [Benzylpenicillin Sodium]			S	Transplacental	Unk		Not Reported	

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

	Flebogamma Dif [Immunoglobulin Human Normal]	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Etamsylate	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Metoprolol Tartrate	S	Transplacental	Unk	Not Reported
	Albumin	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17530878	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- 202002001243			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Hypersensitivity; Nausea; Rheumatoid Arthritis; Urticaria; Vertigo; Weight Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Tylenol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17552501	EXPEDITED (15-DAY)		OT	GB-CELLTRION INC.- 2020GB020489			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection;	Rituximab (Unknown)			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown	Unk		Not Reported

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

Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Mycophenolate	S	Unknown		Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	60 Milligram	Not Reported
	Prednisolone	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17570310	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068426			Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17578248	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS- 2020M1031689		50 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Tamponade; Cardiogenic Shock; Cardiomegaly; Concomitant Disease Aggravated; Dyspnoea Exertional; Dyspnoea Paroxysmal Nocturnal; Electrocardiogram Qrs Complex Abnormal; Heart Sounds Abnormal;	Bosentan			S	Oral	250 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	5 Mg, Qd		Mylan
	Mycophenolate Mofetil			S	Unknown	2.5 G, Qd		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Remodulin			S	Subcutaneous	0.046 Mg, Q1hour		Mylan
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Mylan
	Riociguat			C	Unknown	6 Mg, Qd		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Oedema Peripheral;
Pericardial Effusion;
Pericardiotomy; Pleural
Effusion; Prohormone
Brain Natriuretic Peptide
Increased; Rales; Serositis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17578988	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024680			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Orencia			S	Unknown			Bristol Myers Squibb
	Arava			S	Unknown	20 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17588707	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025879		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Stress	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

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

Methotrexate	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Mefenamic Acid	C	Unknown		Not Reported
Prednisone	C	Oral	6 Milligram, Qd	Not Reported
Tylenol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17588868	EXPEDITED (15-DAY)		DS, HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-0830		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Contraindicated Product	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Administered; Drug Ineffective;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
Gastrointestinal Disorder;	Sulfasalazine			S	Unknown			Not Reported
Hepatic Enzyme Increased; Ileus;	Sulfasalazine			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Enbrel			S	Subcutaneous			Not Reported
Rheumatoid Arthritis; Therapy Non-Responder	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17588873	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1542			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17588875	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1543			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug	Methotrexate (Trade Name			S	Unknown			Not Reported

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

Intolerance; Rheumatoid Arthritis	Unknown)				
	Enbrel	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17588876	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1554			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17588922	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-			Male	CAN

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Detailed Report

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17589340	EXPEDITED (15-DAY)		HO, OT	US-ORION CORPORATION ORION PHARMA-20_00008751		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590071	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-241501		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Microsporidia Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S				Sun
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

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Mycophenolate Mofetil				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590112	EXPEDITED (15-DAY)		HO	CA-SA-2020SA075289			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Off Label Use	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (1 Everyday)		Sanofi	
	Leflunomide			S	Unknown	10 Mg, Qd, Tablet (1 Every 1 Day)		Sanofi	
	Methotrexate			S	Unknown	20 Mg, Qw (1 Every 1 Weeks)		Not Reported	
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	80 Mg/Kg		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Mg, Qow., Solution Subcutaneous		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported	
	Orencia			S				Not Reported	
	Orencia			S	Unknown			Not Reported	
	Orencia			S				Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590113	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075134			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		Unk		Sanofi	
	Atorvastatin Calcium			S				Not Reported	
	Leflunomide			S				Sanofi	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pregabalin	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Sulfasalazine	S		Not Reported
Trichlormethiazide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590114	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA075343			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine			S	Oral	400 Mg		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Sulfasalazine			S	Oral	1 G		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Rituximab			S		Unk		Not Reported
	Prednisone			C		10 Mg		Not Reported
	Prednisone			C		5 Unk		Not Reported
	Simponi			C	Subcutaneous			Not Reported

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

Xeljanz			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590131	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009143		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Gait Disturbance; Wrist Surgery	Meloxicam			S	Unknown	Unk		Apotex	
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported	
	Arava			C	Unknown	Unk		Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA075141			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S				Sanofi	
	Leflunomide			S	Unknown			Sanofi	
	Methotrexate			S				Not Reported	
	Certolizumab Pegol			S	Unknown			Not Reported	
	Golimumab			S				Not Reported	
	Humira			S				Not Reported	
	Infliximab			S				Not Reported	
	Otezla			S				Not Reported	
	Acetaminophen			C				Not Reported	
	Advair			C				Not Reported	
	Allopurinol			C				Not Reported	
	Atrovent Hfa			C				Not Reported	
	Codeine			C				Not Reported	
	Cyclobenzaprine Hydrochloride			C				Not Reported	
	Dilaudid			C				Not Reported	
	Hydromorphone Hydrochloride			C				Not Reported	
	Ibuprofen			C				Not Reported	
	Leucovorin Calcium			C				Not Reported	
	Nexium [Esomeprazole Sodium]			C				Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported	

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Sulfasalazine	C	Not Reported
Ventolin Hfa	C	Not Reported
Xeljanz	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076294			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S				Not Reported
	Lyrica			S	Oral	150 Mg, Bid		Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590399	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076538		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Sodium Aurothiomalate			S		Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590401	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076268			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590669	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS- 2020-AMRX-00900		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Retinal Toxicity	Cyclophosphamide			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Docetaxel			S	Unknown	21-Day Cycle, 4 Cycles		Amneal
	Anastrozole			S	Unknown	21-Day Cycle, 4 Cycles)		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	7.1 Mg/Kg Real Body Weight, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590700	EXPEDITED (15-DAY)		HO	US-GYP-000097		30 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hepatitis; Herpes Simplex; Trichomoniasis	Prednisone	S	Unknown	5 Mg Daily	Geneyork Pharma
	Hydroxychloroquine	S	Unknown	200 Mg Twice Daily	Not Reported
	Metronidazole	S	Oral		Not Reported
	Paracetamol	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591184	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026344		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Orencia			S	Endocervical			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported
	Leflunomide			S	Unknown	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	2 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591627	DIRECT		HO			55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Folliculitis; Oral Disorder; Pharyngeal Disorder; Skin Swelling; Therapy Cessation; Urticaria; Urticaria	Hydroxychloroquine (Plaquenil)			S	Oral			Not Reported
	Pravastatin			C				Not Reported
	Fosomax			C				Not Reported
	Prempro			C				Not Reported
	Premarin			C				Not Reported

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Sipronlactone	C	Not Reported
Minoxidil	C	Not Reported
Doxycycline	C	Not Reported
Omeprazole	C	Not Reported
Singular	C	Not Reported
Ventolin	C	Not Reported
Azelastine	C	Not Reported
B-Complex	C	Not Reported
Triple Omega Fish Oil	C	Not Reported
Calcium	C	Not Reported
Vit. D-3	C	Not Reported
Evening Primrose	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591702	EXPEDITED (15-DAY)		OT	NVSC2020CA083830		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Ovarian Cyst; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stress; Transplant Dysfunction; Transplant Rejection	Methotrexate			S	Unknown	25 Mg, Unknown		Not Reported
	Tacrolimus			S	Oral	2 Mg, Q12h		Novartis
	Tacrolimus			S	Oral	3 Mg, Q12h		Novartis
	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Neoral			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unknown		Not Reported
	Certolizumab Pegol			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxyquinoline Sulfate			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rapamune			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	1 G, Unknown		Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591728	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085589		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein	Ilaris			S	Subcutaneous	Unk		Novartis
Increased; Deep Vein Thrombosis; Diverticulitis;	Ilaris			S				Novartis
Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Methotrexate			S	Unknown	Unk		Not Reported
Increased; Renal Failure; Sepsis; Thrombosis	Methotrexate			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S				Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591840	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026340			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591841	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026360		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Orencia			S	Endocervical			Bristol Myers Squibb
	Actemra			S	Unknown	1 Dosage Form		Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Calcium			C	Unknown	500 Milligram, Qd		Not Reported
	Dorzolamide			C	Unknown	Unk, Bid		Not Reported
	Hydrochloride/Timolol Maleate							
	Ergocalciferol			C	Unknown	Unk, Qwk		Not Reported
	Estradiol			C	Unknown	0.6 Percent, Tid		Not Reported
	Estrogel			C	Unknown	0.6 Percent, Tid		Not Reported
	Furosemide			C	Unknown	40 Milligram, Qd		Not Reported
	Gravol			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown	1500 Milligram, Qd		Not Reported

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Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
Xalatan	C	Ophthalmic	50 Microgram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591924	EXPEDITED (15-DAY)	OT		CA-SA-2020SA076466			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591928	EXPEDITED (15-DAY)	OT		CA-SA-2020SA076322			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Pregabalin			S	Oral	150 Mg, Bid		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Actemra			S				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591942	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085582			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Apparent Death; Deep Vein Thrombosis;	Ilaris	S	Unknown	Unk	Novartis
Diverticulitis; Drug Ineffective; Joint Swelling;	Ilaris	S			Novartis
Off Label Use; Pain;	Leflunomide	S	Unknown	Unk	Not Reported
Pulmonary Embolism;	Leflunomide	S			Not Reported
Renal Failure	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S			Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591972	NON-EXPEDITED			US-SA-2018SA048629			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Liver Function Test Increased	Arava			S	Oral	Unk Unk,Unk		Sanofi	
	Plaquenil			S		Unk Unk,Unk		Sanofi	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17592969	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068673		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	40 Mg		Sanofi
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S		20 Mg		Not Reported
	Methotrexate			S		10 Mg		Not Reported
	Kevzara			S				Sanofi
	Sulfasalazine			S				Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C		10 Mg		Not Reported
	Rabeprazole Sodium			C		20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17593152	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-026342			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported	
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported	
	Myochrysine			S	Intramuscular	25 Milligram, Qwk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17594000	EXPEDITED (15-DAY)		OT	NVSC2020CA083912		74 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma Of Skin; Treatment Failure	Neoral			S	Unknown	125 Mg, Bid, (2 Every 1 Day)		Novartis	
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unknown		Not Reported	
	Arava			S	Unknown	20 Mg, Qd, (Every 1 Day)		Not Reported	
	Azathioprine Sodium			S	Unknown	150 Mg		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Qw, (1 Every 1 Week)		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Imuran			S	Unknown	150 Mg, Tid, (3 Evey 1 Day)		Not Reported	
	Methotrexate			S	Oral	1 Df, Qw, (1 Every 1 Week)		Not Reported	
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1		Not Reported	

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

Sulfasalazine	S	Oral	Day)	Not Reported
Citalopram Hydrobromide	C	Unknown	1 G, Bid, (2 Every 1 Day)	Not Reported
Citalopram Hydrobromide	C	Unknown	40 Mg	Not Reported
Citalopram Hydrobromide	C	Unknown	40 Mg, Qd (Every 1 Day)	Not Reported
Citalopram Hydrobromide	C	Unknown	1 Df, Qw	Not Reported
Prednisone	C	Unknown	10 Mg, Qd (Every 1 Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17594417	EXPEDITED (15-DAY)		DE, HO	NVSC2020CA085101		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C- Reactive Protein	Ilaris			S	Subcutaneous			Novartis
Increased; Deep Vein Thrombosis; Diverticulitis;	Ilaris			S				Novartis
Drug Ineffective;	Methotrexate			S	Unknown			Not Reported
Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain;	Methotrexate			S				Not Reported
Pulmonary Embolism;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Pulmonary Thrombosis;	Rituximab			S				Not Reported
Red Blood Cell Sedimentation Rate	Actemra			S	Unknown			Not Reported
Increased; Renal Failure;	Actemra			S				Not Reported
Sepsis; Thrombosis	Anakinra			S	Unknown			Not Reported
	Arava			S				Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

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	Remicade	S	Unknown	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17594574	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022677			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colonic Abscess; Drug Ineffective; Pruritus	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	350 Milligram		Not Reported
	Humira			S	Unknown	40 Milligram		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	40 Milligram		Not Reported
	Methotrexate			S	Oral	20 Milligram, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Enbrel			C	Unknown	50 Milligram		Not Reported
	Gold			C	Intramuscular	50 Milligram		Not Reported
	Leflunomide			C	Unknown	20 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	17431505	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1186390			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Hydroxychloroquine			S	Unknown			Teva

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Trametinib			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	17595044	EXPEDITED (15-DAY)		OT	IT-ACCORD-177503		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Furosemide			S	Oral			Accord	
	Dabigatran			S				Not Reported	
	Daparox			S				Not Reported	
	Lamictal			S				Not Reported	
	Plaquenil			S				Not Reported	
	Valium			S				Not Reported	
	Sotalol			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	17595150	NON-EXPEDITED			NVSC2020US086178			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Hydroxychloroquine Sulfate			S	Unknown	Unk			Novartis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2020	17597821	DIRECT		DS			61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Eye Disorder; Vascular Device User	Hydroxychloroquine	Y		S	Oral	Quantity:1 Tablet(S);		Unknown	
	Orencia	Y		S	Intramuscular	Quantity:1 Injection(S);Other Frequency:Once A Week;		Er Squibb	
	Heart Meds			C				Not Reported	
	Diabetes Meds			C				Not Reported	
	Inhalers			C				Not Reported	
	Med For Migraines			C				Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2020	17598592	DIRECT		DS			39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Joint Stiffness; Manufacturing Materials Issue; Product Complaint; Product Substitution Issue; Therapy Non-Responder	Hydroxychloroquine 200mg Tab			S				Dr Reddys	
	Omeprazole			C				Not Reported	
	Hydroxychloroquine			C				Not Reported	
	Clarinet			C				Not Reported	
	Turmeric			C				Not Reported	
	Iron			C				Not Reported	
	Mvi			C				Not Reported	
	VitaminD3			C				Not Reported	
	Aleve			C				Not Reported	
	Tylenol			C				Not Reported	
	Pseudoephedrine			C				Not Reported	
	Guaifenesin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	12351402	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2016GSK063971		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Eye Disorder; Gait Disturbance; Gait Inability; Joint Dislocation; Stomatitis	Voltaren			S	Unknown	Unk		Glaxosmithkline	
	Cortisone			S	Unknown	Unk		Not Reported	
	Methotrexate Sodium			S				Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Apo-Diclofenac			S		Unk		Not Reported	
	Desoximetasone			S		Unk		Not Reported	
	Diclofenac Potassium			S		Unk		Not Reported	
	Remicade			C	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	12764755	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-076425			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileus; Intestinal Obstruction; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	12767211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-015691		65 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasia; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	10 Milligram, Bid		Not Reported
	Xeljanz			C	Subcutaneous	Unk		Not Reported
	Desoximetasone			C	Oral	10 Milligram, Qd		Not Reported
	Desoximetasone			C	Oral	5 Milligram 2 Every 1 Day		Not Reported
	Zostavax			C	Subcutaneous	Unk		Not Reported
	Cortisone			C	Oral	10 Milligram, Qd		Not Reported
	Diclofenac			C	Subcutaneous	100 Milligram, Qd		Not Reported
	Voltaren Acti			C	Unknown	100 Milligram, Qd		Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

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Desoximetasone	C	Subcutaneous		Not Reported
Diclofenac	C	Oral	50 Milligram, Bid	Not Reported
Diclofenac	C	Oral	100 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	12771269	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-076855		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasia; Synovitis; Tooth Loss	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous	Unk		Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Diclofenac [Diclofenac Sodium]			C	Subcutaneous	100 Milligram		Not Reported

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

Diclofenac [Diclofenac Sodium]	C	Oral	5 Milligram, Bid	Not Reported
Cortisone	C	Oral	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Oral	10 Milligram, Bid	Not Reported
Cortisone Acetate	C	Subcutaneous	Unk	Not Reported
Desoximetasone	C	Oral	5 Milligram, Bid	Not Reported
Desoximetasone	C	Oral	10 Milligram, Qd	Not Reported
Desoximetasone	C	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	13251617	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006643			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zostavax			S	Subcutaneous	Unk		Not Reported
	Zostavax			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Desoximetasone			C	Oral	Unk		Not Reported

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Diclofenac			C	Unknown	100 Mg, Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	13502224	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017- 1253		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Haematoma; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Naprosyn			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	14547629	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-040466		28 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Sinusitis; Anaphylactic Shock; Anxiety; Bronchitis; Depression; Device Malfunction; Electric Shock; Faeces Soft; Fatigue; Gait Disturbance; Headache; Influenza Like Illness; Long Qt Syndrome; Mouth Ulceration; Nausea; Off Label Use; Pain; Productive Cough; Pyrexia; Seasonal Allergy; Secretion Discharge; Sinusitis; Tongue Ulceration; Upper	Abatacept			S	Intravenous (not otherwise specified)	750 Milligram, Qmo		Bristol Myers Squibb	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Celebrex			C	Unknown	Unk		Not Reported	
	Pantoloc [Pantoprazole]			C	Unknown	Unk		Not Reported	
	Leucovorin [Folinic Acid]			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	Ativan			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Respiratory Tract Infection
Bacterial

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	14918934	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-043916		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Mg, Qwk		Bristol Myers Squibb	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported	
	Humira			S	Subcutaneous	40 Gram		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Tid		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	2000 Milligram		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Parenteral	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Methotrexate			S	Subcutaneous	Unk		Not Reported	
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	2000 Mg, Unk		Not Reported	
	Etanercept			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported	
	Apo-Azathioprine			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Oral	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	

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

Actemra	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Tofacitinib	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Q2wk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	15551969	EXPEDITED (15-DAY)		OT	PHHY2018CA135990		34 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	16387991	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-029881		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Lisinopril Tablet			S	Unknown	Unk		Aurobindo

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

Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Folic Acid Methotrexate Sodium Plaquenil Sulfasalazine Synthroid Tecta Voltaren Sr Xeljanz Depo-Medrol	S S S S S S S S C	Unknown Subcutaneous Oral Oral Unknown Oral Oral Unknown Intramuscular	Unk 20 Milligram, Every Week 200 Milligram, Once A Day 500 Milligram, Once A Day Unk Unk 75 Milligram,As Required 5 Milligram, Two Times A Day Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	16388028	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-029853		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet Diclofenac Potassium Diclofenac Potassium Folic Acid Methotrexate Sodium Plaquenil Plaquenil Sodium Aurothiomalate Sulfasalazine Sulfasalazine Synthroid Tecta Xeljanz			S S S S S S S S S S S S	Unknown Oral Oral Unknown Subcutaneous Oral Oral Unknown Oral Oral Unknown Oral Unknown	Unk 75 Milligram 75 Milligram, Two Times A Day Unk 20 Milligram, Every Week 200 Milligram, Once A Day 400 Milligram, Once A Day Unk 500 Milligram, Once A Day 1 Gram, Two Times A Day Unk Unk 5 Milligram, Two Times A Day		Aurobindo Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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

Depo-Medrol C Intramuscular Unk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	16778008	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-025000		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown			Not Reported
Adverse Event; Alopecia;	Cortisone			S	Oral			Not Reported
Anti-Cyclic Citrullinated	Desoximetasone			S	Unknown			Not Reported
Peptide Antibody Positive;	Topicort			S	Unknown			Not Reported
Arthropathy; Condition	Actemra			S	Unknown			Not Reported
Aggravated;	Apo Hydroxyquine			S	Unknown			Not Reported
Contraindicated Product	Apo-Prednisone			S	Unknown			Not Reported
Administered; Drug	Arava			S	Oral			Not Reported
Ineffective; Drug	Cetirizine Hydrochloride			S	Unknown			Not Reported
Intolerance; Fatigue;	Cetirizine Hydrochloride And			S	Unknown			Not Reported
Glossodynia; Hand	Pseudoephedrine							
Deformity; Hepatic	Cimzia			S	Subcutaneous			Not Reported
Enzyme Increased;	Cortisone Acetate			S	Unknown			Not Reported
Infusion Related Reaction;	Desoximetasone			S	Oral			Not Reported
Joint Swelling; Maternal	Enbrel			S	Subcutaneous			Not Reported
Exposure During	Folic Acid			S	Unknown			Not Reported
Pregnancy; Pain;	Fosamax			S	Oral			Not Reported
Pemphigus; Product Use	Humira			S	Subcutaneous			Not Reported
Issue; Rash; Rheumatoid	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Arthritis; Rheumatoid	Methotrexate			S	Oral			Not Reported
Factor Positive; Swelling;	Methotrexate Sodium			S	Oral			Not Reported
Synovitis; Systemic Lupus	Orencia			S	Subcutaneous			Not Reported
Erythematous; Wound	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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

Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	16792776	EXPEDITED (15-DAY)		OT	PHHY2019CA209333			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cellulitis; Drug Ineffective; Infection	Cosentyx			S	Unknown	150 Mg, Qw		Novartis
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Not Reported
	Plaquenil			S	Oral	200 Mg, Qd		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported
	Prednisone			C	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Q12h		Not Reported

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

Xeljanz	C	Oral	5 Mg, Q12h	Not Reported
Xeljanz	C	Oral	5 Mg, Q8h	Not Reported
Xeljanz	C	Oral	5 Mg, Q12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	16881443	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 28961		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Remicade			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Single-Use Pre-Filled Syringe		Not Reported
	Cimzia			S	Unknown	Unknown, Single-Use Pre-Filled Syringe		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unknown, Aerosol		Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous	Unknown		Not Reported
	Cephalexin			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17467057	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-008069		41 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Alanine Aminotransferase	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb	
Abnormal; Alanine	Adalimumab			S	Subcutaneous	Unk		Not Reported	
Aminotransferase	Apo Ibuprofen			S	Oral	600 Milligram		Not Reported	
Increased; Arthralgia;	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported	
Arthritis; Arthropathy;	Apo-Lefflunomide			S	Oral	Unk		Not Reported	
Aspartate	Apremilast			S	Oral	30 Milligram, Bid		Not Reported	
Aminotransferase	Apremilast			S	Unknown	60 Milligram, Bid		Not Reported	
Increased; Basal Cell	Apremilast			S	Unknown			Not Reported	
Carcinoma; Blood	Arava			S	Oral	20 Milligram, Qd		Not Reported	
Creatinine Increased;	Celebrex			S	Oral	200 Milligram, Bid		Not Reported	
Blood Parathyroid	Certolizumab Pegol			S	Subcutaneous			Not Reported	
Hormone Decreased;	Ciclosporin			S	Oral			Not Reported	
Blood Pressure Systolic	Cimzia			S	Subcutaneous	Unk		Not Reported	
Increased; C-Reactive	Codeine			S	Unknown			Not Reported	
Protein Abnormal;	Cosentyx			S	Unknown			Not Reported	
Decreased Appetite;	Cyclosporin			S	Oral	Unk		Not Reported	
Diarrhoea; Drug Eruption;	Enbrel			S	Subcutaneous	Unk		Not Reported	
Drug Hypersensitivity;	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported	
Drug Intolerance;	Enbrel			S	Unknown	25 Milligram		Not Reported	
Enthesopathy; Erythema;	Golimumab			S	Subcutaneous	Unk		Not Reported	
Fatigue; Fear Of Injection;	Humira			S	Subcutaneous			Not Reported	
General Physical Health	Hydroxychloroquine			S	Unknown			Not Reported	
Deterioration; Granuloma	Ibuprofen			S	Oral	600 Milligram, Every 1		Not Reported	
Skin; Headache;						Days			
Hypercalcaemia;									
Inflammation; Infusion									
Related Reaction;									
Insomnia; Joint Injury;									
Joint Swelling; Loss Of									
Personal Independence In									
Daily Activities;									
Musculoskeletal Stiffness;									
Nausea; Pain; Panniculitis;									
Peripheral Swelling;									

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

Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased;	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
Rheumatoid Arthritis;	Leflunomide	S	Oral		Not Reported
Rheumatoid Nodule; Skin Necrosis; Skin Ulcer;	Methotrexate	S	Oral	Unk, Qwk	Not Reported
Synovitis; Tendonitis;	Motrin Children	S	Oral	600 Milligram	Not Reported
Tenosynovitis; Therapy	Motrin Children	S	Unknown	6 Dosage Form, Qd	Not Reported
Non-Responder; Tongue Disorder; Treatment	Motrin Children	S	Oral	600 Milligram, Qd	Not Reported
Failure; Ulcer; Urticaria	Motrin Children	S	Oral	Unk Milligram, Qd	Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown		Not Reported
	Otezla	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Ustekinumab	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported
	Etanercept	S	Unknown	Unk	Not Reported
	Etanercept	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported

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

Apo-Cyclosporine	S	Oral	Unk	Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	0.6 Milligram	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	Unk, Qwk	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	8 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Vitamin D3	C	Oral	200 International Unit	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17493046	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL		29 YR	Male	GBR

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

INDUSTRIES LTD-
2020R1-238891

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Infarction;	Atorvastatin			S	Unknown	Unk		Sun
Cerebrovascular Accident;	Warfarin			S	Unknown	Unk		Taro
Transient Ischaemic	Clopidogrel			S	Unknown	Unk		Sun
Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17581926	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA083381		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-	Ilaris			S	Unknown			Novartis
Reactive Protein	Ilaris			S				Novartis
Increased; Deep Vein	Ilaris			S	Subcutaneous			Novartis
Thrombosis; Diverticulitis;	Ilaris			S				Novartis
Drug Ineffective; Joint	Methotrexate			S	Unknown			Not Reported
Swelling; Off Label Use;	Methotrexate			S				Not Reported
Pain; Pulmonary	Rituximab			S	Intravenous drip	Unk		Not Reported
Embolism; Pulmonary	Rituximab			S				Not Reported
Thrombosis; Red Blood	Actemra			S	Unknown	Unk		Not Reported
Cell Sedimentation Rate	Actemra			S				Not Reported
Increased; Renal Failure;	Anakinra			S	Unknown			Not Reported
Sepsis; Thrombosis	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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	Hydroxychloroquine Sulfate	S	Unknown	Unk		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade	S				Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk		Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Sulfasalazine	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17584606	EXPEDITED (15-DAY)		OT	NVSC2020US082743		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Microsporidia Infection; Product Use In Unapproved Indication	Mycophenolate Mofetil			S	Unknown	3 G, Qd		Novartis	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596866	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-015777		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Furosemide			S	Unknown	Unk		Aurobindo	
	Dabigatran Etxilate			S	Oral	300 Milligram, Once A Day		Not Reported	
	Daparox			S	Unknown	Unk		Not Reported	
	Lamictal			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Valium			S	Unknown	Unk		Not Reported	
	Sotalol			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596878	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068447			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Actemra			S				Not Reported
	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S	Oral	600 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Folic Acid			C		1 Df, Qw		Not Reported
	Xeljanz			C		5 Mg, Bid		Not Reported
	Xeljanz			C	Oral	5 Mg, Qd		Not Reported
	Prednisone			C				Not Reported
	Simponi			C	Subcutaneous	Solution		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596898	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068448			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Arava			S		Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Folic Acid			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cetirizine			S		Unk		Not Reported

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Cimzia	S	Unk	Not Reported
Etanercept	S	Unk	Not Reported
Fosamax	S	Unk	Not Reported
Humira	S	Subcutaneous	Unk
Orencia	S	Subcutaneous	Unk
Remicade	S	Intravenous (not otherwise specified)	Unk
Rituxan	S	Intravenous (not otherwise specified)	Unk
Simponi	S	Subcutaneous	Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596904	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-241793		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	8.22 Milligram/Kilogram		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596948	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068521		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Arava			S	Unknown			Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi	
	Methotrexate			S	Unknown	20.0 Mg, Qw		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Cimzia			S	Unknown	Dosage Form: Solution Subcutaneous		Not Reported	
	Enbrel			S	Unknown			Not Reported	

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

Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Rituxan	S	Unknown	Dosage Form: Solution Intravenous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596953	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068456			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Leflunomide			S		20 Mg		Sanofi	
	Methotrexate			S		15 Mg, Qw		Not Reported	
	Plaquenil			S		200 Mg, Bid		Sanofi	
	Actemra			S		567 Mg, Qm		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S				Not Reported	
	Celebrex			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596954	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068451			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S				Sanofi	
	Hydroxychloroquine			S		400 Mg, Qd		Sanofi	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596980	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1580			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596997	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068694			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dactylitis; Dermatitis Psoriasiform; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoacusis; Nausea; Psoriatic Arthropathy; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S		10 Mg		Sanofi
	Leflunomide			S		Unk, Qd		Sanofi
	Plaquenil			S		200 Mg, Bid		Sanofi
	Cosentyx			S		150 Mg, Q4w		Not Reported
	Humira			S		400 Mg In 7 Years		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Cymbalta			C		60 Mg, Qd		Not Reported
	Esomeprazole			C	Oral			Not Reported
	Magnesium;Naproxen							
	Tylenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596998	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068558		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>



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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596999	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068621			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia;	Arava			S		Unk		Sanofi	

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Condition Aggravated;	Hydroxychloroquine	S		200 Mg, Qd	Sanofi
Drug Ineffective; Joint	Leflunomide	S	Unknown	20 Mg, Qd	Sanofi
Swelling; Joint Swelling;	Plaquenil	S	Unknown	200 Mg, Qd	Sanofi
Musculoskeletal Disorder;	Plaquenil	S	Unknown	Unk	Sanofi
Nasopharyngitis;	Enbrel	S		Unk	Not Reported
Neutropenia; Platelet	Orencia	S		Unk	Not Reported
Count Decreased;	Xeljanz	S	Oral	5 Mg, Qd	Not Reported
Sinusitis; Sleep Disorder;	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Tendon Disorder;	Advil [Ibuprofen]	C	Unknown	Unk	Not Reported
Thrombocytopenia	Folic Acid	C	Unknown	Unk	Not Reported
	Ketorolac	C		Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Qw	Not Reported
	Naproxen	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597002	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068605			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis;	Arava			S				Sanofi
Treatment Failure	Hydroxychloroquine			S				Sanofi
	Sulfasalazine			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Methotrexate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597003	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068651			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Leflunomide			S		20 Mg, Qd		Sanofi
Rheumatoid Arthritis	Actemra			S				Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported

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	Humira	S	Subcutaneous	40 Mg, Qow		Not Reported
	Methotrexate	S		20 Mg, Qow		Not Reported
	Orencia	S				Not Reported
	Plaquenil	S		200 Mg, Bid		Sanofi
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Bupropion	C				Not Reported
	Sulfasalazine	C				Not Reported
	Xeljanz	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068702			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Dyspepsia; Food Intolerance; Hepatotoxicity; Rash; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Imuran [Azathioprine]			C		Unk		Not Reported
	Methotrexate			C		Unk Unk, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068717		24 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clear Cell Renal Cell Carcinoma; Diarrhoea;	Leflunomide			S		Unk		Sanofi

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Renal Mass; Vomiting	Allopurinol	S	Unknown	Unk	Not Reported
	Folic Acid	S			Not Reported
	Hydroxychloroquine Sulfate	S		Unk	Sanofi
	Prednisone	S		Unk	Not Reported
	Sulfasalazine	S		Unk	Not Reported
	Naproxen	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Oxycodone Hydrochloride	S		Unk	Not Reported
	Azathioprine	S		Unk	Not Reported
	Ciclosporin	S			Not Reported
	Medroxyprogesterone Acetate	S		Unk	Not Reported
	Etanercept	S		25 Mg ,Qw	Not Reported
	Infliximab	S		400 Mg	Not Reported
	Rituximab	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597077	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1212448		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Headache; Palpitations	Risedronate Monosodique			S	Oral	35 Mg		Teva
	Plaquenil			S	Oral	1 Dosageform		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral			Not Reported
	Pantoprazole			C				Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C		500 Mg/25 Mg,		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C				Not Reported
	Diffu K, Gelule			C				Not Reported
	Atorvastatine			C				Not Reported
	Clopidogrel (Chlorhydrate De)			C				Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597242	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025396		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Bone Disorder; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Cefazolin			S	Intramuscular			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Day		Not Reported	
	Leflunomide			S	Oral	10 Milligram		Not Reported	
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			C	Unknown			Not Reported	
	Naproxen			C	Unknown	500 Milligram, 2 Every 1 Day		Not Reported	
	Viread			C	Unknown			Not Reported	
	Xeljanz			C	Oral	5 Milligram, 2 Every 1 Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597342	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068726		80 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Back Pain; Balance Disorder; Cardiac Disorder; Coronary Artery Bypass; Dermatitis	Arava			S				Sanofi	
	Gold Bond			S				Sanofi	
	Humira			S	Subcutaneous			Not Reported	

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Allergic; Drug	Methotrexate	S	Oral	10 Mg	Not Reported
Hypersensitivity; Foot	Plaquenil	S			Sanofi
Deformity; Hand	Arnica Montana	C			Not Reported
Deformity; Infection;	Asa	C			Not Reported
Irritable Bowel Syndrome;	Calcium	C			Not Reported
Lung Neoplasm Malignant;	Folic Acid	C			Not Reported
Pain In Extremity; Surgery;					
Therapeutic Product Effect					
Decreased; Therapeutic					
Product Effect Decreased;					
Therapeutic Product Effect					
Decreased; Toe					
Amputation					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597343	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068740			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein	Leflunomide			S		1 Df (1 Every 1 Days)		Sanofi
Abnormal; Drug	Hydroxychloroquine			S				Sanofi
Ineffective; Herpes Zoster;	Methotrexate			S				Not Reported
Pulmonary Fibrosis;	Sulfasalazine			S		500 Mg, Bid		Not Reported
Rheumatoid Arthritis	Xeljanz			S				Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Lyrica			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597347	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068725			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthrodesis; Drug	Leflunomide			S		20 Mg, Qd		Sanofi
Ineffective; Empyema;	Hydroxychloroquine			S	Urethral	20 Mg, Qd		Sanofi
Foot Deformity; Hand	Ibuprofen			S	Unknown	400 Mg		Not Reported
Deformity; Joint Effusion;								
Joint Stiffness; Limb								

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Operation;	Methotrexate	S		25 Mg, Qw	Not Reported
Musculoskeletal Stiffness;	Methotrexate	S		25 Mg, Qw	Not Reported
Nodule; Pneumonia;	Methotrexate	S		25 Mg, Qw	Not Reported
Rheumatoid Arthritis;	Methotrexate	S		25 Mg, Qw	Not Reported
Scar; Toe Operation	Sulfasalazine	S		2000 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Calcium	C		1200 Mg	Not Reported
	Ergocalciferol	C		2000 Iu, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597348	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068745		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Diarrhoea;	Arava			S				Sanofi
Dyspepsia; Nodule;	Hydroxychloroquine			S				Sanofi
Osteoarthritis; Rheumatoid	Leflunomide			S		20 Mg, Qd		Sanofi
Arthritis; Therapeutic	Methotrexate			S		25 Mg, Qw		Not Reported
Product Effect Decreased	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597350	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068748			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint	Arava			S		Unk		Sanofi
Swelling; Nausea; Pain;	Bacitracin			S	Subcutaneous	Unk		Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine			S		Unk		Sanofi
Therapeutic Product Effect	Methotrexate			S		Unk		Not Reported
Decreased	Neomycin Sulfate			S		Unk		Not Reported
	Polymyxin B Sulfate			S		Unk		Not Reported

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Actemra	S	Subcutaneous	Unk	Not Reported
Prednisone	C	Intramuscular		Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597351	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068446		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Arava			S		Unk Unk, Qd		Sanofi
	Meloxicam			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Sanofi
	Prednisone			S		5 Mg, Qd		Not Reported
	Sulfasalazine			S				Not Reported
	Paracetamol			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597410	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068817			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Fatigue; Hand Deformity; Infection; Pain; Therapy Non-Responder	Leflunomide			S	Unknown	20.0 Mg, Qd		Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg, Qd		Sanofi
	Toradol			S	Unknown			Not Reported
	Methotrexate			C	Unknown	25.0 Mg, Qw		Not Reported
	Sulfasalazine			C		2.0 G, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597412	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068814		59 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pulmonary Fibrosis; Treatment Failure	Arava			S	Oral	Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Desoximetasone			S		Unk		Sanofi
	Leflunomide			S		1 Df, Qd		Sanofi
	Plaquenil			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Intravenous (not otherwise specified)			Sanofi
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S		1 Df, Qw		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597474	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068888			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S	Subcutaneous	1 Df, Qd		Sanofi
	Plaquenil			S		300 Mg, Qd		Sanofi
	Cimzia			S		Unk (Subcutaneous Solution)		Not Reported
	Alendronate Sodium			C	Oral	70 Mg		Not Reported
	Atenolol			C		3 Df		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide;Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium			C	Oral	40 Mg		Not Reported

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Trihydrate	C	Oral	25 Mg, Qd	Not Reported
Hydrochlorothiazide	C	Oral	1 Mg, Qd	Not Reported
Lorazepam	C		Unk	Not Reported
Methotrexate	C	Oral	Unk	Not Reported
Sulfasalazine	C		1 Df, Q12h	Not Reported
Trimebutine	C			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597475	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068908			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Steatosis; Interstitial Lung Disease; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	15 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597476	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068846			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

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	Enbrel	S	Unknown	50 Mg	Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	C		5 Mg, Bid	Not Reported
	Xeljanz	C		11 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597487	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068893			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Peripheral Swelling; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi	
	Hydroxychloroquine Sulfate			S		Unk		Sanofi	
	Methotrexate			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597495	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069320		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Sanofi	
	Hydroxychloroquine			S				Sanofi	
	Naproxen Sodium			S		Unk		Not Reported	
	Prednisone			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S				Not Reported	
	Orencia			S				Not Reported	
	Xeljanz			S				Not Reported	
	Folic Acid			C				Not Reported	
	Methotrexate			C				Not Reported	

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Hydroxychloroquine Sulfate				C	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597496	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069110			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S				Sanofi	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous	Total Daily Dose 40 Mg		Not Reported	
	Hydroxychloroquine			S				Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597501	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069115			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Fatigue; Ill-Defined Disorder; Neuropathy Peripheral; Stomatitis	Leflunomide			S				Sanofi	
	Methotrexate			S				Not Reported	
	Hydroxychloroquine			S				Sanofi	
	Sulfasalazine			S				Not Reported	
	Tocilizumab			S				Not Reported	
	Tofacitinib			S				Not Reported	
	Xeljanz			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597502	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA069085		61 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S		Unk		Sanofi
	Actemra			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S				Not Reported
	Prednisone Acetate			S				Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hydroxychloroquine Sulphate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597503	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069113		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Peripheral Swelling; Rheumatoid Arthritis; Stress	Leflunomide			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	2.5 Mg, Qd		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597507	EXPEDITED (15-DAY)		OT	CA-SA-2020SA069114			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Intolerance; Finger Deformity; Foot Deformity; Gait Disturbance; Infection; Pancytopenia	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi	
	Humira			S	Subcutaneous	40 Mg 1 Every 2 Weeks		Not Reported	
	Methotrexate			S	Oral	7.5 Mg 1 Every 1 Weeks		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Arava			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597724	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085875			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Ilaris			S	Unknown			Novartis	
	Ilaris			S				Novartis	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S				Not Reported	
	Methotrexate			S	Intra-arterial			Not Reported	
	Methotrexate			S				Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Sulfasalazine			S				Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S				Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S				Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

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	Orencia	S							Not Reported
	Humira	S	Subcutaneous						Not Reported
	Humira	S							Not Reported
	Enbrel	S	Unknown						Not Reported
	Enbrel	S							Not Reported
	Anakinra	S	Unknown						Not Reported
	Anakinra	S							Not Reported
	Actemra	S	Unknown						Not Reported
	Actemra	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597887	EXPEDITED (15-DAY)		HO	CA-SA-2020SA069360		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Naproxen Sodium			S				Not Reported
	Prednisone			S				Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17598089	EXPEDITED (15-DAY)		DS, OT	CA-GLAXOSMITHKLINE-CA2020050982		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Malaise;	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac Sodium			S	Oral	75 Mg, Bid		Glaxosmithkline

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Osteoarthritis; Pain; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac Potassium	S	Oral	75 Mg, Prn	Glaxosmithkline
	Pantoprazole	S	Unknown	Unk	Glaxosmithkline
	Pantoprazole	S	Oral	Unk	Glaxosmithkline
	Folic Acid	S	Unknown	Unk	Glaxosmithkline
	Voltaren (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Glaxosmithkline
	Apo - Diclo (Diclofenac Sodium)	S	Oral	75 Mg, Bid	Not Reported
	Apo Lisinopril	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Qd	Not Reported
	Lisinopril	S	Unknown	Unk	Not Reported
	Lisinopril Dihydrate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	2 G, Qd	Not Reported
	Synthroid	S	Oral	Unk	Not Reported
	Tecta	S	Oral	Unk	Not Reported
	Xeljanz	S	Oral	10 Mg, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intramuscular	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17598887	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM- 2020CA1495			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Off Label Use; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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Prednisone			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17599129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571299		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Subcutaneous			Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17599148	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2020126926			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Nausea; Off Label Use; Paraesthesia; Product Use	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Oral	Unk (10mg To 15mg)		Pfizer	
	Methotrexate Sodium			S	Oral	20 Mg, Unk		Pfizer	
	Methotrexate Sodium			S	Oral	25 Mg, Unk		Pfizer	

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Issue; Psoriatic Arthropathy; Rash; Rheumatoid Nodule	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Oral	15 Mg, Unk	Pfizer
	Methotrexate Sodium	S	Subcutaneous	30 Mg, Unk	Pfizer
	Sulfasalazine	S	Unknown	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Unknown	2 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	4 G, 1x/Day	Pfizer
	Sulfasalazine	S	Unknown	3 G, 1x/Day	Pfizer
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Cosentyx	S	Intramuscular	300 Mg, Unk	Not Reported
	Cosentyx	S	Oral	40 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Leflunomide	C		10 Mg, Unk	Not Reported
	Leflunomide	C		20 Mg, Unk	Not Reported
	Tocilizumab	C	Subcutaneous	162 Mg, Weekly	Not Reported
	Abatacept	C	Subcutaneous	125 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17599397	NON-EXPEDITED		OT	US-APPCO PHARMA LLC-2082107			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Suspected Product Contamination	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17600334	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026570		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17600344	EXPEDITED (15-DAY)		OT	CA-SA-2020SA076298		80 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi	
	Arava			S	Unknown	Unk		Sanofi	

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Leflunomide	S	Unknown	Tablet	Sanofi
Methotrexate	S	Unknown	20 Mg, Qw	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Actemra	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Orencia	S			Not Reported
Allopurinol	C	Unknown	200 Mg, Qd (1 Every 1 Day)	Not Reported
Prednisone	C		5 Mg, Bid	Not Reported
Prednisone	C		10 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17600442	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076641			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting;	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Naproxen			S		Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			S	Oral	3 Mg Bid		Not Reported
	Prednisone			S	Oral	5 Mg Bid		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Qw		Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S		Unk (Suspension Intra-Articular)		Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Triamcinolone Acetonide			S				Sanofi
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported

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Wheelchair User	Enbrel	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Immunoglobulins Nos	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Infliximab	S		5 Mg	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Triamcinolone	S	Subcutaneous	25 Mg, Qow	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17600446	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA076650			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Hydroxychloroquine Sulfate			S		5 Mg/Kg, Qd		Sanofi	
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	
	Prednisone			S	Oral	5 Mg, Bid		Not Reported	
	Prednisone			S	Oral	3 Mg, Bid		Not Reported	
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported	
	Triamcinolone Acetonide			S	Unknown			Sanofi	
	Adalimumab			S	Subcutaneous			Not Reported	
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported	
	Enbrel			S	Subcutaneous	12.5 Mg		Not Reported	
	Enbrel			S	Subcutaneous	25 Mg		Not Reported	
	Intravenous Immunoglobulin			S	Intravenous (not otherwise specified)	70 G		Not Reported	
	Infliximab			S	Unknown	5 Mg		Not Reported	
	Infliximab			S	Intravenous (not	3 Mg/Kg, Qw		Not Reported	

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Synovitis; Underdose; Vomiting	Orencia	S	otherwise specified)						
			Intravenous (not otherwise specified)	250 Mg, Qm					Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17600447	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076649			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5.0 Mg/Kg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	15 Mg/M2, Qw		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Prednisone			S	Oral	3 Mg, Bid		Not Reported
	Prednisone			S		5 Mg, Bid		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Qw		Not Reported
	Enbrel			S		12.5 Mg, Qw		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Infliximab			S		5 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17600654	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-		34 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Infliximab			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported
	Cimzia			S	Unknown	Unknown		Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Otezla			S	Oral	Unknown		Not Reported
	Otezla			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Rituximab			S	Unknown	Unknown		Not Reported
	Simponi			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Penicillin			C	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17601616	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 10007		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Etanercept			S	Unknown	Unknown		Not Reported

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Abdominal Pain Upper; Arthralgia; Cardiac Failure Congestive; Cough; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Gastric Disorder; Hepatic Steatosis; Hypertension; Malaise; Nausea; Rash; Therapeutic Product Effect Decreased	Arava	S	Unknown	Unknown	Not Reported
	Biaxin	S	Unknown	Unknown	Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unknown	Not Reported
	Ciprofloxacin	S	Unknown	Unknown	Not Reported
	Clindamycin Phosphate	S	Unknown	Unknown	Not Reported
	Codeine	S	Unknown	Unknown	Not Reported
	Enalapril	S	Unknown	Unknown	Not Reported
	Fosamax	S	Unknown	Unknown	Not Reported
	Hctz	S	Unknown	Unknown	Not Reported
	Hydralazine Hydrochloride	S	Unknown	Unknown	Not Reported
	Levaquin	S	Unknown	Unknown	Not Reported
	Losartan	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Metoprolol Tartrate	S	Unknown	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unknown	Not Reported
	Pariet	S	Unknown	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Cipro [Ciprofloxacin]	C	Unknown	Unknown	Not Reported
	Esomeprazole	C	Unknown	Unknown	Not Reported
	Gold	C	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unknown	Not Reported
	Iron Sucrose	C	Unknown	Unknown	Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17602693	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026610		65 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17605425	DIRECT	Y	DE, LT			87 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Test Positive; Cough; Electrocardiogram Qt Prolonged; Urine Odour Abnormal	Hydroxychloroquine			S				Not Reported
	Azithromycin 250 Mg Tablet			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	13350239	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008095		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities;	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Prednisone			S	Unknown	2 Df, Unk		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	2 Df, Q.O.D.		Not Reported

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

Neurogenic Bladder; Pollakiuria; Product Dose Omission; Product Dose Omission	Folic Acid	S	Unknown	Unk, Q.Wk.	Not Reported
	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Apotex
	Actemra	S	Subcutaneous	162 Mg, Q.Wk.	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	281 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	281 Mg	Not Reported
	Arava	S	Oral	20 Mg, Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, 1 Every 2 Weeks	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Methotrexate	C	Unknown	25 Mg, Q.Wk.	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	15711597	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-113698		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, Q2wk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, Q2wk		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported

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

Methotrexate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Q2wk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
Leflunomide	S	Oral	10 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Viread	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16079854	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 05830		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug	Infliximab			S	Unknown	Unknown		Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not	Unknown, Powder For		Not Reported	

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

Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Remicade	S	otherwise specified)	Solution Intravenous	
			Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
Renal Impairment;	Enbrel	S	Unknown		Not Reported
Rheumatoid Arthritis;	Enbrel	S	Subcutaneous	Duration 705	Not Reported
Therapeutic Product Effect Decreased; Therapeutic Response Decreased;	Enbrel	S	Subcutaneous		Not Reported
Treatment Failure	Enbrel	S	Unknown	Unknown	Not Reported
	Actemra	S	Unknown	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Azathioprine	S	Unknown	Unknown	Not Reported
	Ciclosporin	S	Unknown	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown. Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Gold	S	Intramuscular	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S			Not Reported
	Apo-Azathioprine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported

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

Rituximab	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Anakinra	S	Unknown	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16079890	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019- 06218		9 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Arthropathy; C-Reactive Protein Increased;	Adalimumab			S	Subcutaneous			Not Reported	
Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use In	Adalimumab			S	Unknown	Unknown		Not Reported	
	Etanercept			S	Subcutaneous			Not Reported	
	Infliximab			S	Unknown	Unknown		Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Abatacept			S	Unknown	Unknown		Not Reported	
	Actemra			S	Unknown	Unknown		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown	Unknown		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown	Unknown		Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown	Unknown		Not Reported	
	Orencia			S				Not Reported	
	Plaquenil			S	Unknown	Unknown		Not Reported	

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

Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16085223	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019- 06099		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S				Not Reported
	Adalimumab			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
	Humira			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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

Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16094586	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA057581		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Rheumatoid Arthritis; Seronegative Arthritis; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk Unk, Qw		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

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Naprosyn	C	Unknown	Unk	Not Reported
Erythromycin	C	Unknown	Unk	Not Reported
Morphine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16443477	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018- 03342		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Etanercept			S	Unknown	Unknown		Not Reported
Adverse Drug Reaction;	Adalimumab			S	Subcutaneous	Unknown		Not Reported
Adverse Event; Adverse	Actemra			S	Unknown	Unknown		Not Reported
Reaction; Arthralgia;	Arava			S	Oral	Unknown		Not Reported
Contraindicated Product	Arava			S	Unknown	Unknown		Not Reported
Administered; Drug	Certolizumab Pegol			S	Subcutaneous	Unknown		Not Reported
Ineffective; Dyspepsia;	Cimzia			S	Subcutaneous	Unknown		Not Reported
Fatigue; Gastric Disorder;	Cimzia			S	Unknown	Unknown		Not Reported
General Physical Health	Cimzia			S	Subcutaneous	Unknown Solution		Not Reported
Deterioration; Insomnia;	Enbrel			S	Unknown			Not Reported
Joint Swelling; Malaise;	Enbrel			S	Unknown	Unknown		Not Reported
Nausea; Off Label Use;	Humira			S	Subcutaneous			Not Reported
Pain; Product Use In	Humira			S	Subcutaneous	Unknown		Not Reported
Unapproved Indication;	Humira			S	Unknown	Unknown		Not Reported
Rash; Rheumatoid	Leflunomide			S	Unknown	Unknown		Not Reported
Arthritis; Sleep Disorder	Leflunomide			S				Not Reported
	Minocycline Hydrochloride			S	Unknown	Unknown		Not Reported
	Myochrysine			S	Intramuscular	Unknown Solution		Not Reported
	Myochrysine			S	Subcutaneous	Unknown		Not Reported
	Myochrysine			S	Parenteral	Unknown Solution Intramuscular		Not Reported
	Myochrysine			S	Unknown	Unknown		Not Reported

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

Myochrysine	S	Intramuscular	Unknown	Not Reported
Orencia	S	Unknown		Not Reported
Otezla	S	Oral	Unknown	Not Reported
Otezla	S	Unknown	Unknown	Not Reported
Rituxan	S	Intravenous drip	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Sirukumab	S	Unknown	Unknown	Not Reported
Sirukumab	S			Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown Solution	Not Reported
Stelara	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Tofacitinib Citrate	S	Oral		Not Reported
Ustekinumab	S	Unknown	Unknown	Not Reported
Ustekinumab	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Intravenous drip	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Minocycline	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown Solution	Not Reported
Simponi	S	Unknown	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Salazopyrin	S	Unknown	Unknown	Not Reported
Apremilast	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported

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Minocin	S	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Orencia	C	Unknown	Unknown	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown Powder For Solution	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	C	Unknown	Unknown	Not Reported
Orencia	C	Unknown		Not Reported
Plaquenil	C	Unknown	Unknown	Not Reported
Salazopyrin	C	Unknown	Unknown	Not Reported
Rheumatrex	C	Unknown	Unknown	Not Reported
Abatacept	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16788654	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA249407		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac			S	Ophthalmic	Unk		Not Reported
Alopecia; Anti-Cyclic	Sulfasalazine			S	Oral	500 Mg		Not Reported
Citrullinated Peptide	Sulfasalazine			S	Oral	1000 Mg, Q12h		Not Reported
Antibody Positive;	Topicort			S	Cutaneous	Unk		Sanofi
Arthropathy;	Prednisone			S	Oral	Unk		Not Reported
Contraindicated Product	Prednisone			S	Oral	Unk		Not Reported
Administered; Discomfort;	Leflunomide			S	Oral	Unk		Sanofi
Drug Ineffective; Drug	Arava			S	Oral	Unk		Sanofi
Intolerance; Duodenal	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
Ulcer Perforation; Fatigue;	Cetirizine			S	Unknown	10 Mg		Not Reported
Glossodynia; Hand	Hydrochloride/Pseudoephedrine							
Deformity; Helicobacter								
Infection; Hepatic Enzyme								
Increased;								
Hypersensitivity; Infusion								

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Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Hydrochloride	S	Topical	25 Mg	Not Reported
	Cortisone Acetate	S	Oral	Unk	Sanofi
	Desoximetasone	S	Unknown	5 Mg	Not Reported
	Folic Acid	S	Unknown	1 Mg	Not Reported
	Folic Acid	S	Oral	Unk	Not Reported
	Alendronate Sodium	S	Oral	Unk	Sanofi
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Unknown	Unk	Sanofi
	Pseudoephedrine Hydrochloride	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Rituxan	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Oral	400 Mg, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Subcutaneous	40 Mg	Not Reported
	Humira	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S			

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Sulfathalidine	S	Oral	500 Mg	Not Reported
Sulfathalidine	S	Oral	1000 Mg, Q12h	Not Reported
Tofacitinib	S	Unknown	5 Mg, Q12h	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Q12h	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16877937	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019- 28737		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral	Unknown		Not Reported	
	Ciclosporin			S	Oral	Unknown		Not Reported	
	Ciclosporin			S	Unknown	Unknown		Not Reported	
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported	
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported	
	Imuran			S	Unknown	Unknown		Not Reported	
	Methotrexate			S	Subcutaneous	Unknown		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown	Unknown		Not Reported	
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported	

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

Apo-Leflunomide	S	Unknown		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Simponi	S	Unknown	Unknown, Solution Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Xeljanz	S	Oral		Not Reported
Piroxicam	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	16906473	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-201909001003			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Arava			S	Unknown	Unk,		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17194720	EXPEDITED (15-DAY)		HO, OT	US-ADVANS PHARMA-201912002914			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthma;	Hydroxychloroquine			S	Unknown	Unk, Plaquenil		Concordia
Asthma; Chest Discomfort;	Prednisone			S	Unknown			Not Reported
Chest X-Ray Abnormal;	Sulfasalazine			S	Unknown	Unk, Qd (1in 1d)		Not Reported
Fall; Glaucoma; Joint	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 2 Wk)		Not Reported
Swelling; Macular	Humira 40mg/0.8ml			S	Subcutaneous	Unk, Weekly, (1 In 1 Wk),		Not Reported
Degeneration;	Humira 40mg/0.8ml			S	Subcutaneous	Unk,Solution For Infusion		Not Reported
Musculoskeletal Disorder;	Humira 40mg/0.8ml			S	Subcutaneous	In Pre-Filled Syringe		Not Reported
Musculoskeletal Pain;	Humira 40mg/0.8ml			S	Subcutaneous	(1 In 1 Wk)		Not Reported
Nausea; Pneumonia;	Humira			S	Subcutaneous	Citrate Free		Not Reported
Pyrexia; Respiratory Tract	Iron			C	Unknown	Unk		Not Reported
Infection Bacterial; Retinal	Folic			C	Unknown	Unk		Not Reported
Toxicity; Rib Fracture;	Eliquis			C		Unk		Not Reported
Therapeutic Response	Prilosec			C		Unk		Not Reported
Shortened; Wheelchair	Zantac			C		Unk		Not Reported
User; White Blood Cell	Losartan			C		Unk		Not Reported
Count Increased	Flexeril			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17287199	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2020-00706			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Infliximab			S	Intravenous (not			Not Reported
Antibody Test Positive;	Infliximab			S	otherwise specified)			Not Reported
Arthralgia; Arthritis;	Infliximab			S	Intravenous (not			Not Reported
Arthropathy; Body Height	Infliximab			S	otherwise specified)			Not Reported
Below Normal; Bone	Infliximab			S	Unknown			Not Reported
Density Decreased; C-								

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

Reactive Protein Increased; Condition Aggravated;	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Contraindicated Product Administered; Diarrhoea;	Adalimumab	S	Subcutaneous	Unknown	Not Reported
Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive;	Adalimumab	S	Subcutaneous	Unknown	Not Reported
Hypocalcaemia; Hypokalaemia;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Hypotension;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Immunodeficiency; Joint Destruction; Joint Effusion;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal;	Anakinra	S	Subcutaneous		Not Reported
Loss Of Consciousness;	Anakinra	S	Unknown		Not Reported
Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea;	Anakinra	S	Subcutaneous		Not Reported
Obesity; Off Label Use;	Anakinra	S	Subcutaneous		Not Reported
Pleural Effusion;	Anakinra	S	Subcutaneous		Not Reported
Polyarthritis; Product Use Issue; Psoriasis; Pyrexia;	Enbrel	S	Subcutaneous	Unknown	Not Reported
Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock;	Enbrel	S	Subcutaneous		Not Reported
Synovitis; Therapeutic Product Effect Decreased;	Enbrel	S	Subcutaneous		Not Reported
Therapy Non-Responder;	Humira	S	Subcutaneous	Unknown	Not Reported
Underdose; Vomiting;	Hydroxychloroquine Sulfate	S	Oral		Not Reported
Wheelchair User	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
	Intravenous Immunoglobulin	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported

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Naproxen Sodium	S	Unknown	Unknown	Not Reported
Naproxen Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Apo-Naproxen	S	Unknown	Unknown	Not Reported
Apo-Naproxen	S			Not Reported
Apo-Prednisone	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Gamastan	S	Intramuscular		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)		Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Naproxen	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Triamcinolone	S	Unknown	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-arterial	Unknown Suspension Intra Articular	Not Reported

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

	Triamcinolone Acetonide	S	Intra-arterial	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17521215	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1193557		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Paradoxical Drug Reaction; Sleep Disorder; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Unknown			Teva	
	Prednisone			S	Unknown	40 Milligram Daily;		Actavis	
	Prednisone			S	Unknown	Tapered Down From 40 Mg/Day To 20 Mg/Day Over The Previous 4 Weeks		Actavis	
	Azathioprine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17557563	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318947			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Simponi			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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	Celebrex		C	Unknown				Not Reported	
	Lyrica		C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17601958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571285			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Celebrex			C	Unknown			Not Reported	
	Leflunomide			C	Unknown			Not Reported	
	Sulfasalazine			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17602357	NON-EXPEDITED			US-APPCO PHARMA LLC-2082131		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma	
	Synthroid			C	Unknown			Not Reported	
	Januvia			C	Unknown			Not Reported	
	Olmesartan Medoxomil And Hydrochlorothiazide			C	Unknown			Not Reported	
	Troujeo			C	Unknown			Not Reported	
	Ezetimibe			C	Unknown			Not Reported	

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Vitamin B Complex			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17602740	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003001986			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17603176	EXPEDITED (15-DAY)		HO	NVSC2020CA086171		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Delirium;	Cosentyx			S	Unknown	Unk		Novartis	
Dislocation Of Vertebra;	Methotrexate			S	Unknown	Unk		Not Reported	
Drug Hypersensitivity;	Leflunomide			S	Unknown	Unk		Not Reported	
Drug Ineffective; Drug	Rituximab			S	Unknown	Unk		Not Reported	
Intolerance; Drug	Enbrel			S	Unknown	Unk		Not Reported	
Tolerance Decreased;	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
Infection; Seronegative	Orencia			S	Unknown	Unk		Not Reported	
Arthritis; Therapeutic	Simponi			S	Subcutaneous	Unk		Not Reported	
Product Effect Decreased;	Sulfasalazine			S	Unknown	Unk		Not Reported	
Type 2 Diabetes Mellitus;	Naproxen			C	Unknown	Unk		Not Reported	
Wound Infection									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17603214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-025877			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Back Injury;	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Drug Ineffective; Fall;	Arava			S	Unknown	20 Milligram		Not Reported	
Headache; Injury; Nausea;									

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

Treatment Failure; Vomiting	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605057	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA076608		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthritis; Body Height Below Normal; Bone Density Decreased; Diarrhoea; Dizziness; Drug Ineffective; Human Antichimeric Antibody Positive; Nausea; Obesity; Septic Shock; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	3 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605175	EXPEDITED (15-DAY)		OT	CA-SA-2019SA247463			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Cardiomyopathy;	Plaquenil	S		Unk	Sanofi
Depression; Drug	Arava	S		Unk Unk, Unk	Sanofi
Ineffective; Drug	Buprenorphine	C		10 Ug, Qd	Not Reported
Intolerance;	Xarelto	C		15 Mg, Qd	Not Reported
Hypersensitivity;	Bisoprolol	C		12.5 Mg, Qd	Not Reported
Myelopathy; Neuropathy	Lasix [Furosemide Sodium]	C		20 Mg (20mg Od/Q2days Depending On Need)	Not Reported
Peripheral	Lasix [Furosemide Sodium]	C		Unk	Not Reported
	Vitamin D [Vitamin D Nos]	C		Unk	Not Reported
	Vitamin B12 Nos	C		Unk	Not Reported
	Vitamin B6	C		Unk	Not Reported
	Fish Oil	C		Unk Unk, Unk	Not Reported
	Calcium	C		Unk Unk, Unk	Not Reported
	Magnesium	C		Unk Unk, Unk	Not Reported
	Ramipril	C		12.5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Prednisone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605363	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 09913		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Infliximab			S	Unknown	Unknown		Not Reported
Adverse Drug Reaction;	Actemra			S	Unknown	Unknown		Not Reported
Alanine Aminotransferase	Apo-Hydroxyquine			S	Unknown			Not Reported
Increased; Alopecia;	Apo-Prednisone			S	Unknown			Not Reported
Anxiety; Arthralgia;	Enbrel			S	Subcutaneous			Not Reported
Aspartate	Humira			S	Subcutaneous			Not Reported
Aminotransferase	Humira			S	Subcutaneous			Not Reported
Increased; Asthenia;	Hydroxychloroquine			S	Unknown			Not Reported
Depression; Diarrhoea;								
Drug Dependence; Drug								
Ineffective; Drug								

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

Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown	Unknown	Not Reported
	Desoximetasone	C	Unknown	Unknown	Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605416	DIRECT	Y	DE			41 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Cardiac Arrest; Coronavirus Infection; Pneumonia; Renal Failure; Ventricular Tachycardia	Hydroxychloroquine			S	Oral		5 DAY	Not Reported	
	Acetaminophen			C				Not Reported	
	Ceftriaxone			C				Not Reported	
	Cisatracurium			C				Not Reported	
	Doxycycline			C				Not Reported	
	Fentanyl			C				Not Reported	
	Heparin			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Midazolam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605439	DIRECT	Y	LT			85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Tachycardia	Plaquenil			S	Oral	Other Frequency:Load - Then 200mg;		Not Reported	
	Azithromycin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605541	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP009047			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hepatotoxicity; Rash	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk. (Therapy Duration 365 Unit Unspecified)		Not Reported	
	Infliximab			S	Unknown	5 Mg/Kg, One Every Eight Week		Not Reported	

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Methotrexate	S	Unknown	15 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	Unk, Qd	Not Reported
Rituximab	C	Intravenous (not otherwise specified)	1 G, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605719	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10553		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution For Infusion		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605780	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200331857		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Cataract;	Remicade			S	Intravenous (not			Not Reported

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

Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Desoximetasone Orencia Plaquenil /00072602/ Sulfasalazine Metformin Hydrochloride Humira Altace Asa Ergocalciferol Folic Acid Methotrexate Rosuvastatin Calcium D-Alpha Tocopherol	S S S S S S C C C C C C C	otherwise specified) Unknown Unknown Unknown Unknown Subcutaneous Oral	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605804	EXPEDITED (15-DAY)		OT	US-APPCO PHARMA LLC-2082143			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17606206	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT- 1212925		75 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematochezia	Furosemide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Teva
	Dabigatran Etexilate			S	Oral	300 Mg		Not Reported
	Daparox			S	Unknown			Not Reported
	Lamictal			S	Unknown			Not Reported
	Valium			S	Unknown			Not Reported
	Sotalol			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17606630	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-025455		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; C- Reactive Protein	Orencia			S	Unknown			Bristol Myers Squibb	
Abnormal; Chest Pain;	Azathioprine			S	Unknown			Not Reported	
Drug Intolerance;	Ciclosporin			S	Unknown			Not Reported	
Dyspnoea; Elbow	Enbrel			S	Unknown			Not Reported	
Deformity; Fatigue; Jaw	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Fracture; Joint Swelling;	Methotrexate			S	Unknown			Not Reported	
Musculoskeletal Pain;	Mycophenolate Mofetil			S	Unknown			Not Reported	
Neck Pain; Overlap	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Syndrome; Pain In									
Extremity; Pain In Jaw;									
Red Blood Cell									
Sedimentation Rate	Xeljanz			C	Unknown			Not Reported	
Abnormal; Sle Arthritis;									
Toxicity To Various									
Agents; Weight Decreased									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17606828	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA085981		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Bone	Cosentyx			S	Unknown	Unk		Novartis	
Disorder; C-Reactive	Adalimumab			S	Subcutaneous	Unk		Not Reported	
Protein Abnormal; Drug	Leflunomide			S	Oral	Unk Unk, Bid		Not Reported	
Eruption; Drug Ineffective;	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported	
Fall; Fatigue; Femur	Actemra			S	Unknown	Unk		Not Reported	
Fracture; Fracture	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported	
Delayed Union; Impaired	Apo-Prednisone			S	Unknown	Unk		Not Reported	
Healing; Intentional	Enbrel			S	Subcutaneous	Unk		Not Reported	
Product Use Issue; Joint									
Laxity; Limb Deformity;									
Loose Body In Joint;									
Malaise; Multiple									

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

Fractures; Off Label Use;	Humira	S	Subcutaneous	40 Mg, Unknown	Not Reported
Osteoporosis;	Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
Osteoporotic Fracture;	Naproxen	S	Unknown	Unk	Not Reported
Pain; Rash; Red Blood	Naproxen Sodium	S	Unknown	Unk	Not Reported
Cell Sedimentation Rate	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Abnormal; Synovitis	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	2 Df, Qd	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Insulin	C	Oral	Unk	Not Reported
	Metformin	C	Unknown	2 Df, Bid	Not Reported
	Plaquenil	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17608508	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-015824		54 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Aurobindo
	Plaquenil			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Pantoprazole			C	Unknown	Unk		Not Reported
	Izalgi			C	Unknown	Unk		Not Reported
	Levothyrox			C	Unknown	Unk		Not Reported

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Diffu K	C	Unknown	Unk	Not Reported
Atorvastatine	C	Unknown	Unk	Not Reported
Clopidogrel Hydrochloride	C	Unknown	Unk	Not Reported
Procoralan	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17611030	DIRECT	Y	DE, DS, LT			61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Electrocardiogram Qt Prolonged; Pneumonia Viral	Plaquenil			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15620857	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2556897-00		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Condition Aggravated;	Humira			S	Subcutaneous			Not Reported
Contraindicated Product	Humira			S	Subcutaneous			Not Reported
Administered; Cutaneous Vasculitis; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Ineffective; Drug	Anakinra			S	Subcutaneous			Not Reported
Intolerance; Infiltration	Anakinra			S	Subcutaneous			Not Reported
Anaesthesia; Knee	Apo-Leflunomide			S	Oral			Not Reported
Arthroplasty; Mouth	Enbrel			S	Subcutaneous			Not Reported
Ulceration; Off Label Use;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Oral Mucosal Exfoliation;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Osteoarthritis; Rash;								
Rheumatoid Arthritis;								
Rheumatoid Factor								
Positive; Secretion								
Discharge; Spinal								
Stenosis; Synovitis;	Methotrexate			S	Oral			Not Reported
Vasculitic Rash	Methotrexate			S	Oral			Not Reported

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Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15626375	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555933-00		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Mobicox			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15668473	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570151-00		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Humira			S	Subcutaneous			Not Reported

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

Emotional Disorder;	Actemra	S	Unknown	Not Reported
Herpes Zoster;	Apo-Hydroxyquine	S	Oral	Not Reported
Hypothyroidism; Immobile;	Enbrel	S	Subcutaneous	Not Reported
Inappropriate Schedule Of	Methotrexate	S	Oral	Not Reported
Product Administration;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Injury; Lymphadenectomy;	Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
Malignant Melanoma; Off	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Label Use; Product Dose	Rituximab	S	Unknown	Not Reported
Omission; Rheumatoid	Hydroxychloroquine	S	Unknown	Not Reported
Arthritis; Sensitivity To	Folic Acid	C		Not Reported
Weather Change; Toe	Prednisone	C	Oral	Not Reported
Amputation	Restasis	C		Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15712088	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588120-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Contraindicated	Humira			S	Subcutaneous			Not Reported
Product Administered;	Actemra			S	Unknown			Not Reported
Drug Ineffective;	Arava			S	Unknown			Not Reported
Fibromyalgia; Hernia;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Hypertension;	Methotrexate			S	Unknown			Not Reported
Hypoglycaemia;	Orencia			S	Unknown			Not Reported
Lymphoma; Thyroid	Prednisone			S	Unknown			Not Reported
Disorder	Remicade			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous drip	Powder For Solution Intravenous		Not Reported

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

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15712568	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587985-00		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Humira			S	Subcutaneous			Not Reported
Arthropathy;	Actemra			S	Unknown			Not Reported
Contraindicated Product	Arava			S	Unknown			Not Reported
Administered; Drug	Celebrex			S	Oral			Not Reported
Hypersensitivity; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Dyspnoea;	Methotrexate			S	Unknown			Not Reported
Gait Disturbance; Ill-	Orencia			S	Unknown			Not Reported
Defined Disorder; Lung	Plaquenil			S	Unknown			Not Reported
Disorder; Lupus-Like	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Syndrome;	Toradol			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Pain; Quality Of Life	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Decreased; Rheumatoid	Prednisone			C	Unknown			Not Reported
Arthritis; Therapy Non-	Tramadol			C	Unknown			Not Reported
Responder; Tuberculin								
Test Positive								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15713594	EXPEDITED (15-DAY)		HO	CA-ABBVIE-18K-028-2583819-00			Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15738111	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2594168-00		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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Meloxicam			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	15741654	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594158-00		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	16156007	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2728799-00		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Septra	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	16798598	EXPEDITED (15-DAY)		OT	CA-SA-2019SA250726		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral	Unk		Sanofi
	Desoximetasone			S	Oral	Unk		Sanofi
	Cortisone Acetate			S	Oral			Not Reported
	Diclofenac Sodium			S				Not Reported
	Topicort			S				Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Prednisone			S				Not Reported
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine			S				Not Reported
	Hydrochloride/Pseudoephedrine							
	Hydrochloride							
	Folic Acid			S		1 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S		400 Mg, Qd		Sanofi
	Prednisone			S				Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Sarilumab			S				Sanofi
	Sulfasalazine			S	Subcutaneous	1 G, Bid		Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Desoximetasone			S				Sanofi
	Actemra			S				Not Reported

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

Cortisone Acetate	S		Unk	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Reactine [Cetirizine Hydrochloride]	S		10 Mg, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	S			Not Reported
Leflunomide	C			Not Reported
Atasol [Paracetamol]	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	16805660	EXPEDITED (15-DAY)	DE		CA-TEVA-2019-CA-1108101		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort	Alendronate Sodium			S	Unknown			Actavis	
	Atorvastatin Calcium			S	Unknown			Teva	
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Teva	
	Metformin			S	Unknown	1000 Milligram Daily;		Not Reported	
	Omeprazole Magnesium			S	Oral			Teva	
	Furosemide			S	Unknown			Not Reported	
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis	
	Flovent			S	Unknown			Not Reported	

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

Lasix	S	Unknown		Not Reported
Nitrazadon	S	Unknown		Not Reported
Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
Salmeterol Xinafoate	S	Unknown		Not Reported
Tylenol	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17430893	NON-EXPEDITED			NVSC2020US036804			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
B-Lymphocyte Abnormalities; Foetal Exposure During Pregnancy	Rituximab			S	Transplacental	Maternal Dose: 500 Mg/M2		Not Reported
	Azathioprine			S	Transplacental	Maternal Dose: 100 Mg, Bid		Not Reported
	Prednisone			S	Transplacental	Maternal Dose: 5 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 20 Mg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 1 Mg/Kg, Qd		Novartis
	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 3micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1.5 Micrograms/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 2 Microgram/Kg		Not Reported
	Romiplostim			S	Transplacental	Maternal Dose: 1microgram/Kg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 10mg		Not Reported
	Dexamethasone			S	Transplacental	Maternal Dose: 40 Mg		Not Reported

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Belimumab	S	Transplacental	Maternal Dose: Unk, Qmo	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 1000 Mg/Kg	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 400 Mg/Kg	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 200 Mg/Kg	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Q2w	Not Reported
Iviglob-Ex	S	Transplacental	Maternal Dose: 500 Mg/Kg, Tiw	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17432480	NON-EXPEDITED			NVSC2020US036797		29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Rituximab			S	Intravenous (not otherwise specified)	500 Mg/M2		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Novartis
	Prednisone			S	Unknown	20 Mg, Qd		Novartis
	Prednisone			S	Oral	1 Mg/Kg Qd		Novartis
	Prednisone			S	Unknown	10 Mg Qd		Novartis
	Azathioprine			S	Unknown	100 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Romiplostim			S	Subcutaneous	3 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	1.5 Micrograms/Kg, Qw		Not Reported
	Romiplostim			S	Unknown	2 Micrograms/Kg		Not Reported
	Romiplostim			S	Unknown	1 Microgram		Not Reported
	Belimumab			S	Unknown	Unk Unk, Qmo		Not Reported

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Dexamethasone	S	Unknown	10 Mg	Not Reported
Dexamethasone	S	Oral	40 Mg	Not Reported
Iviglob-Ex	S	Unknown	500 Mg/Kg	Not Reported
Iviglob-Ex	S	Unknown	1000 Mg/Kg	Not Reported
Iviglob-Ex	S	Unknown	400 Mg/Kg	Not Reported
Iviglob-Ex	S	Unknown	200 Mg/Kg	Not Reported
Iviglob-Ex	S	Unknown	500 Mg/Kg, Tiw	Not Reported
Iviglob-Ex	S	Unknown	500 Mg/Kg, Q2w	Not Reported
Iviglob-Ex	S	Unknown	500 Mg/Kg, Tiw	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17570316	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008939		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex	
	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	

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Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Arthrotec	C	Oral	Unk	Not Reported
Arthrotec	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Imuran /00001501/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17571510	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008899			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported	
	Sarilumab			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17586904	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-024281		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb	
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported	
	Actemra			S	Unknown	360 Milligram, Qmo		Not Reported	
	Alendronic Acid			S	Unknown	70 Milligram, Qwk		Not Reported	

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

Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine Enbrel Humira Hydroxychloroquine Sulfate Leflunomide Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Myochrysine Remicade Rituximab Sulfasalazine Ciclosporin Prednisone Xeljanz	S S S S S S S S S S S S S S C C C	Unknown Unknown Subcutaneous Unknown Unknown Unknown Subcutaneous Oral Unknown Subcutaneous Intramuscular Intravenous (not otherwise specified) Intravenous drip Unknown Unknown Unknown Unknown	Unk 25 Milligram, Qwk 40 Milligram, Q2wk Unk Unk 12.5 Milligram, Qwk 15 Milligram, Qwk 10 Milligram, Qwk 12 Milligram, Qwk 17.5 Milligram, Qwk 50 Milligram, Qmo Unk 1000 Milligram, Bid Unk 150 Milligram, Qd Unk Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608636	EXPEDITED (15-DAY)		OT	FR-FERRINGPH-2020FE01903		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia	Menopur			S	Subcutaneous			Ferring
	Plaquenil			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608696	EXPEDITED (15-DAY)		OT	IT-BAXTER-2020BAX006523		75 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Haematochezia	Diretif 10 Mg/MI Soluzione Iniettabile	S	Unknown	Claris
	Dabigatran Etxilate	S	Oral	Not Reported
	Daparox	S	Unknown	Not Reported
	Lamictal	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Valium	S	Unknown	Not Reported
	Sotalol	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608746	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003001933			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anterior Chamber Disorder; Blindness; Epstein-Barr Virus Infection; Eye Pain; Eye Pain; Intraocular Pressure Increased; Necrotising Retinitis; Ocular Hyperaemia; Retinal Detachment; Scleral Disorder; Uveitis; Varicella Zoster Virus Infection; Vision Blurred; Vitreous Floaters; Vitritis	Hydroxychloroquine			S	Unknown	200 Mg, Qd, Tablet		Concordia
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Cellcept			S	Unknown	1000 Mg, Bid		Not Reported
	Valacyclovir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608765	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1216776			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis	Atorvastatin			S				Teva
	Methotrexate			S				Barr
	Plaquenil			S		400 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported

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

Alprazolam	C		Not Reported
Folic Acid	C		Not Reported
Naprosyn	C	1000 Milligram Daily;	Not Reported
Pantoloc	C		Not Reported
Prednisone	C	5 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608937	EXPEDITED (15-DAY)		DS, HO, OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB- 000912			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congestive Cardiomyopathy; Dyspnoea; Left Ventricular Dysfunction	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Qd		Ipsa
	Fexofenadine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Novo Nordisk Pharms Novofem			C	Unknown	Unk		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Lansoprazole			C	Unknown	Unk		Not Reported
	Clonazepam			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported
	Hyoscine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17609386	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA086791		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio	Meperidine Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Novartis
	Bisoprolol			S	Unknown	Unk		Novartis

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Levofloxacin	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Mg, Qw	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	5 Mg	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17609994	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-177659		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Pneumonia	Methotrexate			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17610209	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020050661		75 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Haematochezia	Lamotrigine	S	Unknown	Unk	Glaxosmithkline
	Furosemide	S	Unknown	Unk	Glaxosmithkline
	Daparox	S	Unknown	Unk	Glaxosmithkline
	Valium	S	Unknown	Unk	Glaxosmithkline
	Plaquenil	S	Unknown	Unk	Not Reported
	Dabigatran Etxilate	S	Oral	300 Mg, Qd	Not Reported
	Sotalol	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17610630	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026351		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Cefazolin			S	Unknown	Unk		Not Reported
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks		Not Reported
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 1 Every 2 Weeks		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, 1every One Week		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported

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

Arava	C	Unknown	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Viread	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611049	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-09980			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine Phosphate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported

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

	Naproxen	C	Unknown	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown		Not Reported
	Rituxan	C	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611066	DIRECT	Y	DS, OT			76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Immunosuppressant Drug Level Increased	Plaquenil Azithromycin 500 Mg Iv			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611141	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10625			Female	CAN

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

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611326	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600430			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611609	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 10259			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Disease Recurrence; Drug	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown	Unknown		Not Reported

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Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown	Unknown	Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611785	EXPEDITED (15-DAY)		OT	IT-VALIDUS PHARMACEUTICALS LLC-IT-2020VAL000236			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematochezia	Furosemide			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Not Reported
	Diazepam			S	Unknown	Unk		Not Reported
	Sotalol Hydrochloride			S	Unknown	Unk		Not Reported
	Dabigatran			S	Oral	Unk		Not Reported

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Daparox /00830803/

S

Unknown

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17614765	DIRECT	Y	DE, LT			65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Cytokine Storm; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	Other Dose:400-200 Mg;		Not Reported
	Haldol			C				Not Reported
	Calcium Carbonate			C				Not Reported
	Cefepime			C				Not Reported
	Chlorhexidine			C				Not Reported
	Cistaracurijm			C				Not Reported
	Docusate Sodium			C				Not Reported
	Exoxaparin			C				Not Reported
	Fentanyl			C				Not Reported
	Heparin			C				Not Reported
	Versed			C				Not Reported
	Propofol Continuous Infusion			C				Not Reported
	Pantoprazole			C				Not Reported
	Sennosides			C				Not Reported
	Sertraline			C				Not Reported
	Darunavir/Cobistat			C				Not Reported
	Apixaban			C				Not Reported
	Aspirin			C				Not Reported
	Donepezil			C				Not Reported
	Ketoconazole 2% Shampoo			C				Not Reported
Nitroglycerin SI			C				Not Reported	
Sertraline			C				Not Reported	
Sevelamer			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	11626328	EXPEDITED (15-DAY)		DS, LT, OT	CA-UCBSA-2015032127		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Anti-Cyclic Citrullinated	Cimzia			S	Subcutaneous	Dosage Form: Solution		Not Reported
	Cimzia			S				Not Reported
	Cetirizine Hydrochloride			S		10 Mg, Unk		Not Reported

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

Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product	Cetirizine Hydrochloride	S		Unk	Not Reported
Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased;	Cetirizine Hydrochloride	S	Oral	10 Milligram, Once Daily (Qd)	Ucb
Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Oral	10 Milligram	Ucb
	Cetirizine Hydrochloride	S		Unk	Ucb
	Zyrtec-D	S		10 Mg, Unk	Not Reported
	Zyrtec-D	S			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		Controlled Release Tablets	Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S			Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		25 Milligram, Ointment	Ucb
	Cirrus	S		Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S		5 Mg, Unk	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		500 Milligram	Not Reported
	Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
	Prednisone	S		Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S		Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
	Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported

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

Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Arava	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Humira	S	Subcutaneous	40 Mg (0.8 MI)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S		25 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported

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

Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Pseudoephedrine Hydrochloride	S		1 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		25 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S		10 Milligram	Not Reported
Pseudoephedrine Hydrochloride	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Topicort	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral		Not Reported
Diclofenac Sodium	S		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported

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

Xeljanz	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Adalimumab	S		Unk	Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Actemra	S	Subcutaneous		Not Reported
Actemra	S			Not Reported
Cortisone	S	Oral		Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Cortisone Acetate	S			Not Reported
Cortisone Acetate	S	Oral		Not Reported
Desoximetasone	S		Cutaneous Route	Not Reported
Desoximetasone	S	Oral		Not Reported
Diclofenac	S			Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S			Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Humira	S	Sunconjunctival	Unk Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravesical		Not Reported
Sarilumab	S			Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S		Unk	Not Reported
Topicort	S	Cutaneous		Not Reported
Hydrocortisone Acetate	S	Subcutaneous		Not Reported

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

Golimumab	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Leflunomide	S			Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol	C		Unk	Not Reported
Tofacitinib Citrate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	13058846	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015717		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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

Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	13516082	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038066		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Off Label Use; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	13669856	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA106082		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy;	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi	

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

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Plaquenil	S	Unknown	Unk Unk,Unk	Sanofi
	Hydroxychloroquine	S	Unknown	Unk, Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Unk	Sanofi
	Methotrexate	S	Unknown	Unk Unk, Unk	Not Reported
	Leflunomide	S	Unknown	Unk Unk, Unk	Sanofi
	Methotrexate	S			Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S	Unknown	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Xeljanz	C	Oral	5 Mg,Bid	Not Reported
	Prednisone	C	Unknown	5 Mg,Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	14217330	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025441		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Orencia			S				Not Reported	

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

	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S			Not Reported
	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Simponi	C	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	15509701	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016273080		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Dysphagia; Gastroesophageal Reflux Disease; Glaucoma; Pharyngeal Swelling	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Plaquenil			S		200 Mg, 2x/Day		Not Reported	
	Plaquenil			S		200 Mg, 2x/Day		Not Reported	
	Atorvastatin			C		20 Mg, Unk		Not Reported	
	Latanoprost			C		Unk [125mg/2.5ml]		Not Reported	
	Stiolto Respimat			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	15620477	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2555079-00		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Healing; Multiple	Leflunomide	S	Unknown	Not Reported
Fractures; Osteoporosis;	Naproxen	S	Unknown	Not Reported
Pain; Rash; Red Blood	Orencia	S	Unknown	Not Reported
Cell Sedimentation Rate	Prednisone	S	Unknown	Not Reported
Abnormal; Surgery;	Xeljanz	S	Oral	Not Reported
Synovitis	Aleve	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	15627967	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2558814-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product	Humira			S	Subcutaneous			Not Reported
Administered; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Ineffective;	Apo-Leflunomide			S	Unknown			Not Reported
Hypersensitivity;	Apo-Leflunomide			S				Not Reported
Rheumatoid Arthritis;	Enbrel			S	Unknown			Not Reported
Therapeutic Product Effect	Methotrexate			S	Unknown			Not Reported
Decreased	Methotrexate			S				Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

Etanercept	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	15635108	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2556219-00		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Dysphonia; Gait Disturbance; Hospitalisation; Joint Swelling; Loss Of Consciousness; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Rheumatoid Arthritis; Secretion Discharge; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Warfarin			S	Unknown			Not Reported
	Apo-Warfarin			S				Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Warfarin	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Amitriptyline	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	15728721	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17K-028-1969198-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
Arthralgia; Arthralgia;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
Diarrhoea; Drug	Actemra			S	Unknown			Not Reported	
Hypersensitivity; Infection;	Arava			S	Unknown			Not Reported	
Joint Swelling; Lower	Arava			S	Unknown			Not Reported	
Respiratory Tract	Arava			S	Unknown			Not Reported	
Infection; Nausea;	Cimzia			S	Subcutaneous			Not Reported	
Palpitations; Pulmonary	Cimzia			S	Unknown			Not Reported	
Mass; Rheumatoid	Enbrel			S	Unknown			Not Reported	
Arthritis; Therapeutic	Enbrel			S	Unknown			Not Reported	
Product Effect Decreased	Enbrel			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not			Not Reported	

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			otherwise specified)	
Rituxan	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	For 8 Years	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	For 8 Years	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Vitamin D3	C			Not Reported
Imuran	C			Not Reported
Gold	C			Not Reported
Arthrotec	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	15732982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-17P-028-1858378-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

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Incomplete	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Naproxen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	16337732	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-048239		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Ibuprofen			S	Oral	600 Milligram		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Unknown	60 Milligram		Not Reported
	Apremilast			S	Unknown			Not Reported
	Apremilast			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

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Daily Activities; Nausea;	Humira	S	Unknown		Not Reported
Panniculitis; Peripheral	Hydroxychloroquine	S	Unknown		Not Reported
Swelling; Psoriatic	Infliximab	S	Oral		Not Reported
Arthropathy; Rash; Rash	Leflunomide	S	Oral		Not Reported
Pruritic; Red Blood Cell	Methotrexate	S	Unknown	15 Milligram,1 Every 1 Week	Not Reported
Sedimentation Rate;	Methotrexate	S	Unknown	17.5 Milligram, 4 Every1week	Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Unknown	12 Milligram,4every1week	Not Reported
Rheumatoid Nodule; Skin	Methotrexate	S	Unknown	10 Milligram,4every 1week	Not Reported
Necrosis; Skin Ulcer;	Methotrexate	S	Unknown	12.5 Milligram,4every 1week	Not Reported
Synovitis; Tendonitis;	Methotrexate	S	Unknown	70 Milligram,1every1week	Not Reported
Tenosynovitis; Tongue	Otezla	S	Unknown		Not Reported
Disorder; Ulcer	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram,2every1day	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	25 Milligram,2every1week	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Benadryl [Diphenhydramine]	C	Unknown		Not Reported

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Hydrochloride]				
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Uloric	C	Unknown	80 Milligram,2every1day	Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	16527868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555951-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	Solution-Dosage Form (Form Of Administration)		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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Rituximab	S	Intravenous drip	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	16568503	EXPEDITED (15-DAY)		HO, OT	PHHY2019PL128630		35 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn	Erelzi			S	Intravenous (not otherwise specified)	50 Mg, Unk		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Erelzi			S	Subcutaneous	50 Mg, Qw		Novartis
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	10 Mg, Qd		Not Reported
	Encorton			S	Unknown	15 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	20 Mg, Qd		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Metex			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Folic			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	16820135	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA- GSH201804-001105			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Dizziness; Fatigue; Hepatomegaly; Malaise; Nausea; Pain In Extremity; Puncture Site Pain; Rash; Splenomegaly; Systemic Lupus Erythematosus; Vein Disorder; Vessel Puncture Site Bruise; Vessel Puncture Site Swelling	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Cerezyme			S	Intravenous drip	Dose/Unit: 3200.00 Frequency: Q2		Not Reported	
	Cerezyme			S	Intravenous (not otherwise specified)	3200 Mg, Qow		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17566404	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200318840		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive; Treatment Failure	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S				Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported		

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	Hydroxychloroquine Sulfate	S						Not Reported
	Hydroxychloroquine Sulfate	S	Unknown					Not Reported
	Ergocalciferol	C						Not Reported
	Imuran /00001501/	C	Unknown					Not Reported
	Arthrotec	C	Unknown					Not Reported
	Vitamin D3	C	Unknown					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17575062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008919			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17609231	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002203			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

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02-Apr-2020	17609364	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003002205			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Oral	400 Mg To 600 Mg		Concordia	
	Dabrafenib			S		150 Mg, Bid		Not Reported	
	Trametinib			S		2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17609365	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003002204			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Oral	400 Mg To 600 Mg		Concordia	
	Dabrafenib			S		150 Mg, Bid		Not Reported	
	Trametinib			S		2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17611781	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003002279			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Oral	400 Mg To 600 Mg		Concordia	
	Dabrafenib			S		150 Mg, Bid		Not Reported	
	Trametinib			S		2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17611782	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003002280			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia	

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	Dabrafenib	S	Oral	150 Mg, Bid	Not Reported				
	Trametinib	S		2 Mg, Qd	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17611783	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002281			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia	
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported	
	Trametinib			S		2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17613937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2572186			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Localised Infection; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Gold			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17614080	EXPEDITED (15-DAY)		OT	AU-ADVANZ PHARMA-202003002074			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Disorder; Organ Transplant; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk (For Over 30 Years)		Concordia	
	Cellcept			S	Unknown	500 Mg, Tid (For 1.5 Years)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17614116	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-10342			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis; Weight Increased	Etanercept			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Unknown, Solution		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	
	Methotrexate			S	Unknown	Unknown		Not Reported	
	Orencia			S	Unknown	Unknown		Not Reported	
	Prednisone			S	Unknown	Unknown		Not Reported	
	Rituximab			S	Unknown	Unknown		Not Reported	
	Sulfasalazine			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17614240	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0121425			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Stiffness; Joint Swelling; Pain; Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Lyrica			S	Unknown			Not Reported	

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

Methotrexate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Trichlormethiazide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17614467	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-026601		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Fluctuation; Blood Pressure Increased;	Orencia			S	Unknown			Bristol Myers Squibb
Colitis; Dental Caries;	Amlodipine Besilate			S	Oral	5 Milligram, Qd		Not Reported
Diabetes Mellitus	Asacol			S	Unknown	800 Milligram, Tid		Not Reported
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Diamicron			S	Unknown			Not Reported
Gastrointestinal Disorder; Haematochezia;	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
Hypertension;	Gliclazide			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Humira			S	Subcutaneous			Not Reported
Pain In Extremity;	Leflunomide			S	Unknown			Not Reported
Peripheral Swelling;	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
Rheumatoid Arthritis;	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Vitamin D Deficiency; Weight Increased	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diphenhydramine			C	Oral	50 Milligram		Not Reported
	Ebastine			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

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

	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
	Rosuvastatin Calcium	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616393	DIRECT					63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Substitution Issue; Vertigo	Hydroxychloroquine 200 Mg Tablets			S	Oral	Quantity:180 Tablet(S);		Zydus Pharm
	Norvas			C				Not Reported
	Hctz			C				Not Reported
	Potassium Chloride			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Predinsdone			C				Not Reported
	Pravastatin			C				Not Reported
	General Vitamin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616524	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001- 20-509		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis Infective; Cat Scratch Disease; Complication Associated With Device	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Westward
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616629	DIRECT		OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Rash; Visual Impairment	Hydroxychloroquine	S	Quantity:1 Tablet(S);	Sandoz
	Valsartan	C		Not Reported
	Metoprolol	C		Not Reported
	Atorvastatin	C		Not Reported
	Levothyroxine	C		Not Reported
	Hydrochlorothiazide	C		Not Reported
	Apsirin	C		Not Reported
	Women'S Silver Centrum	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616815	DIRECT	Y	OT			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Hydroxychloroquine			S	Oral			American Health
	Atorvastatin 40mg			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616895	EXPEDITED (15-DAY)		OT	NVSC2020GB089786		43 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Cutaneous Lupus Erythematosus;	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Novartis
Cutaneous Lupus Erythematosus; Disease Progression; Madarosis; Mucosal Pain; Product Use In Unapproved Indication; Skin Plaque	Hydroxychloroquine			S	Transdermal	200 Mg, Qd		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3348747-00		57 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

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Zitromax			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17629156	DIRECT	Y				22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Hydroxychloroquine			S	Subcutaneous			Abbvie	
	Humira			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	12994284	EXPEDITED (15-DAY)		OT	CA-SA-2016SA199672		68 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk,Unk		Sanofi	
	Methotrexate			S	Unknown	20 Mg,Qw		Not Reported	
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi	
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported	
	Orencia			S	Unknown	750 Mg, Qw		Not Reported	
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported	
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	13660454	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1724612US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actonel			S	Unknown	35 Mg, Q Week		Allergan	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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

Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Unk	Not Reported
Plaquenil	S	Unknown	300 Mg, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Cyclical	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	300 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk Unk, Qd	Not Reported
Risedronic Acid	S	Unknown	Unk	Not Reported
Risedronic Acid	S	Unknown	35 Mg, Q Week	Not Reported
Risedronic Acid	S	Unknown	35 Mg, Q Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15108418	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0726		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Headache; Migraine; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection	Kineret			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Meloxicam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15619709	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555775-00		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Allergy To Vaccine;	Humira	S	Subcutaneous	Not Reported
Diarrhoea; Drug	Enbrel	S	Subcutaneous	Not Reported
Ineffective; Fall;	Methotrexate	S	Oral	Not Reported
Hypersensitivity; Larynx	Plaquenil	S	Unknown	Not Reported
Irritation; Nausea; Product	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Use Issue; Pruritus;	Zostavax	S	Subcutaneous	Not Reported
Rheumatoid Arthritis;	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Weight Decreased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15620439	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556971-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Humira			S	Subcutaneous			Not Reported
Drug Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
Intolerance; Non-	Apo-Azathioprine			S	Unknown			Not Reported
Hodgkin'S Lymphoma;	Enbrel			S	Unknown			Not Reported
Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

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Xeljanz		C		Unknown		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15621423	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557292-00		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Contraindicated Product Administered; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Indomethacin			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Apo-Prednisone			S	Oral			Not Reported	
	Apo-Prednisone			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Radioactive Gold			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Indometacin			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Cymbalta	C	Oral	Not Reported
Folic Acid	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15621502	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557034-00		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Humira			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Tofacitinib	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15622316	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557239-00		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Impaired Work Ability; Nasopharyngitis; Nasopharyngitis; Rheumatoid Arthritis; Rheumatoid Arthritis; Stress; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15629333	EXPEDITED (15-DAY)		CA, DS, HO, OT	CA-ABBVIE-18K-028-2557519-00		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Solution		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Foa-Solution		Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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

Infliximab	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Oral	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15662825	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-18K-028-2569806-00		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein Increased;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective;	Humira 40mg/0.8ml			S				Not Reported
Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Arava			S	Nasal			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Ilaris			S	Subcutaneous	Ilaris Single-Use Vial		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S		Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15663251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570496-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15717406	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2587385-00		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Mobicox			C				Not Reported

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

Remicade			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15811306	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617216-00		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Amino	Humira			S	Subcutaneous			Not Reported	
transferase Increased; Aspartate	Actemra			S	Unknown			Not Reported	
Amino transferase Increased; Basal Cell	Actemra			S	Unknown			Not Reported	
Carcinoma; Blood Parathyroid Hormone	Alendronate Sodium			S	Unknown			Not Reported	
Decreased; C-Reactive Protein Increased;	Ciclosporin			S	Unknown			Not Reported	
Contraindicated Product Administered; Drug	Codeine			S	Unknown			Not Reported	
Eruption; Drug Hypersensitivity; Drug	Enbrel			S	Subcutaneous			Not Reported	
Ineffective; Drug Tolerance Decreased;	Hydroxychloroquine			S	Unknown			Not Reported	
Erythema; Granuloma Skin; Hypercalcaemia;	Leflunomide			S	Unknown			Not Reported	
Hypersensitivity; Inflammation; Infusion	Methotrexate			S	Subcutaneous			Not Reported	
Related Reaction; Infusion Related Reaction; Loss Of	Methotrexate			S	Unknown			Not Reported	
Personal Independence In Daily Activities;	Methotrexate			S	Unknown			Not Reported	
Panniculitis; Peripheral Swelling; Product Use	Methotrexate			S	Subcutaneous			Not Reported	
Issue; Rash; Rash Pruritic; Rheumatoid Arthritis;	Methotrexate			S	Oral			Not Reported	
Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Methotrexate			S	Subcutaneous			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	

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

Apo-Leflunomide	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Alendronate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Ciclosporin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15930868	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2655637-00		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Kineret	S	Subcutaneous	Not Reported
Desoximetasone	C		Not Reported
Methotrexate	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	15994348	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2674858-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Surgery; Synovitis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16079906	EXPEDITED (15-DAY)		HO, LT, OT	CA-SAMSUNG BIOEPIS-SB-2019-05955		3 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Product Use	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Adalimumab			S	Unknown	Unknown		Not Reported	
	Adalimumab			S	Subcutaneous	Unknown		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S				Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Anakinra			S	Unknown	Unknown		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Immune Globulin(Human)			S	Intravenous (not otherwise specified)			Not Reported	
	Immune Globulin(Human)			S	Unknown	Unknown		Not Reported	
	Immune Globulin(Human)			S	Intravenous (not otherwise specified)			Not Reported	

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

In Unapproved Indication; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non- Responder; Underdose; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Naproxen	S			Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Other	Unknown	Not Reported
	Triamcinolone	S	Unknown	Unknown	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Unknown	Not Reported
	Apo-Naproxen	S			Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intramuscular	Liquid Intramuscular	Not Reported
	Tocilizumab	S	Unknown	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported

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

Folic Acid	C	Unknown	Unknown	Not Reported
Triamcinolone Hexacetonide	C	Intra-articular	Unknown, Injectable Suspension	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16444293	EXPEDITED (15-DAY)	OT		CA-ABBVIE-19K-028-2822475-00		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported

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

Actemra	S	Subcutaneous		Not Reported
Actonel	S	Unknown		Not Reported
Apo-Leflunomide	S	Oral	Cyclical	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Arava	S	Oral		Not Reported
Risedronate	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Risedronate Sodium	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16567681	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074636			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Back Pain; Drug Ineffective; Enthesopathy; Hla Marker Study Positive; Pancytopenia; Spinal Pain; Spondyloarthropathy; Synovial Disorder	Diclofenac Sodium			S	Unknown	150 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Naproxen			S	Unknown	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Hydroxychloroquine			C	Unknown	400 Milligram Daily;		Not Reported
	Leflunomide			C	Unknown			Not Reported
	Piroxicam			C	Unknown	20 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	20 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16686320	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-21297		67 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis; Walking Aid User	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Rituximab			S	Intravenous (not	Unknown		Not Reported

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

Rituximab	S	otherwise specified)	Unknown	Not Reported
Atorvastatin	C	Intravenous (not otherwise specified)	Unknown	Not Reported
Atorvastatin	C	Unknown	Unknown	Not Reported
Atorvastatin Calcium	C	Unknown	Unknown	Not Reported
Pantoloc	C	Unknown	Enteric-Coated	Not Reported
Pantoloc	C	Unknown	Unknown	Not Reported
Pantoloc	C	Unknown	Unknown	Not Reported
Pantoprazole	C	Unknown	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unknown	Not Reported
Plaquenil	C	Oral		Not Reported
Plaquenil	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16687965	EXPEDITED (15-DAY)		OT	CA-SA-2019SA210544		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Arava			S		366 Unk		Sanofi
	Plaquenil			S		Unk		Sanofi
	Pregabalin			S		150 Mg		Not Reported
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S		1000 Mg, Bid		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S				Not Reported
	Xeljanz			S		Unk		Not Reported
	Rituxan			S		1000 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	1000 Unk		Not Reported

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Infliximab	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
Trazodone	C		200 Mg, Qd	Not Reported
Lumigan Rc	C	Ophthalmic	1 Df, Qd	Not Reported
Suphedrine [Pseudoephedrine Hydrochloride]	C		10 Mg, Qd	Not Reported
Tylenol [Paracetamol]	C		Unk	Not Reported
Tylenol [Paracetamol]	C		3000 Mg, Qd	Not Reported
Valsartan	C		1 Df, Qd	Not Reported
Valsartan	C		Unk	Not Reported
Wellbutrin	C		300 Mg, Qd	Not Reported
Esomeprazole	C		40 Mg, Qd	Not Reported
Nexium [Esomeprazole Sodium]	C		40 Mg, Qd	Not Reported
Tylenol Extra Strength	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16720242	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217291			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Joint Swelling; Ocular Toxicity; Rheumatoid Arthritis	Arava			S	Oral	10 Mg, Qd		Sanofi
	Diclofenac			S	Unknown	50 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Prior To 2011)		Sanofi
	Indometacin			S		50 Mg, (20 To 50 Mg) Tid		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd (Prior To 2016)		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	15 Mg, (10 To 15 Mg) Qw (Prior To 2011)		Not Reported
	Naproxen			S	Unknown	500 Mg, Q6h		Not Reported
	Plaquenil			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

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

Xeljanz	S	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16923698	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA- 2019VAL000576			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S		Unk		Not Reported
	Diphenhydramine Hydrochloride			S		Unk		Not Reported
	Celecoxib			S	Oral	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001502/			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Unk		Not Reported
	Xeljanz			S	Oral	5 Unk		Not Reported
Ezetrol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17199927	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028- 3206389-00			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intestinal Perforation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17559777	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP008882			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex	
	Leflunomide			S	Oral	20 Mg, Qd		Apotex	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17571111	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP008956		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
	Leflunomide			S	Oral	20 Mg, Qd		Apotex	
	Leflunomide			S	Oral	20 Mg, Q.O.Wk.		Apotex	
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Unk		Not Reported	
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported	
	Enbrel			S				Not Reported	

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	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	12.5 Mg, Unk	Not Reported
	Methotrexate	S	Oral	12.5 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qd	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, 1 Every 4 Weeks	Not Reported
	Orencia	S	Unknown	500 Mg, Unk, 1 Every 4 Weeks	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17575454	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP008927		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Mg, Qd		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17611780	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202003002282			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported
	Trametinib			S		2 Mg, Qd		Not Reported

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17611784	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003002283			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia	
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported	
	Trametinib			S		2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17611792	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003002284			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S		400 Mg To 600 Mg		Concordia	
	Dabrafenib			S	Oral	150 Mg, Bid		Not Reported	
	Trametinib			S		2 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17618992	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-202003001932			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Eye Injury; Fatigue; Headache; Therapeutic Response Delayed; Therapeutic Response Shortened; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Leflunomide			S	Unknown	Unk (Or, Dose, Frequency, Route Lot Number And Expiry Date Unknown)		Not Reported	
	Actemra			S	Unknown	Unk (Suspended On 25-Feb-2020)		Not Reported	
	Sulfasalazine			C		Unk		Not Reported	
	Humira			C		Unk		Not Reported	
	Enbrel			C		Unk		Not Reported	
	Methotrexate			C		Unk		Not Reported	

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Pantoloc			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17619006	EXPEDITED (15-DAY)		DS	CA-ADVANZ PHARMA-202003001934			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Diarrhoea; Drug Ineffective; Liver Disorder; Loss Of Personal Independence In Daily Activities; Oral Herpes	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			C				Not Reported	
	Orencia			C				Not Reported	
	Methotrexate			C		Unk		Not Reported	
	Voltaren			C		Unk		Not Reported	
	Leucovorin			C		Unk		Not Reported	
	Iron			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17620210	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009225		82 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Cataract; Contraindicated Product Administered; Dermatitis Allergic; Drug Ineffective; Drug Intolerance; Hepatotoxicity; Nasopharyngitis; Osteoarthritis; Pneumocystis Jirovecii Pneumonia; Rheumatoid Arthritis; Treatment Failure; Urticaria	Leflunomide			S	Oral	Unk		Apotex	
	Enbrel			S	Unknown	Unk		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported	
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported	
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported	
	Sulfasalazine			S	Unknown	750 Mg, Qd		Not Reported	
	Hydrochlorothiazide W/Lisinopril			C	Unknown	Unk		Not Reported	

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	Hydrochlorothiazide W/Lisinopril Dihydrate	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Rituxan	C	Unknown	Unk	Not Reported
	Tylenol Extra Strength	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17620886	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1493			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Ankylosing Spondylitis; Condition Aggravated;	Kineret			S				Not Reported
Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying;	Actemra			S	Unknown			Not Reported
Influenza; Off Label Use; Renal Impairment;	Arava			S	Unknown			Not Reported
Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Mg 1 Every 2 Weeks		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17622122	EXPEDITED (15-DAY)		OT	CA-ROCHE-2573031			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Eye Injury; Fatigue; Headache; Liver Disorder; Therapeutic Product Effect Decreased; Ulcer Haemorrhage	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	20 Mg Was Reduced To 7.5 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
Humira			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17622228	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217086			Female	CAN

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

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

Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17622407	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217045		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Diclofenac			S	Unknown			Actavis
Arthralgia; Asthenia; Blood	Diclofenac			S	Unknown			Actavis
Cholesterol Increased;	Diclofenac			S	Unknown			Actavis
Condition Aggravated;	Amitriptyline			S	Unknown			Not Reported
Disease Recurrence; Drug	Azathioprine			S	Unknown			Not Reported
Ineffective; Drug	Celecoxib			S	Unknown			Teva
Interaction; Drug	Celecoxib			S	Unknown			Teva
Intolerance;	Leflunomide			S	Unknown			Barr
Gastrooesophageal Reflux	Methotrexate			S	Intravenous (not otherwise specified)			Barr
Disease; Impaired Work	Methotrexate			S	Unknown			Barr
Ability; Malaise; Mobility	Methotrexate			S	Parenteral			Barr
Decreased; Movement	Methotrexate			S	Subcutaneous			Barr
Disorder; Muscle Spasms;	Naproxen			S	Unknown			Teva
Off Label Use; Pain; Pain	Pregabalin			S	Unknown			Teva
In Jaw; Product	Prednisone			S	Unknown			Actavis
Complaint; Rash;	Actemra			S	Unknown			Not Reported
Rheumatoid Arthritis;	Allopurinol			S	Unknown			Not Reported
Swelling; Synovitis;	Amitriptyline			S	Unknown			Not Reported
Therapeutic Response	Amitriptyline			S	Unknown			Not Reported
Decreased; Wrist	Hydrochloride/Perphenazine			S	Unknown			Not Reported
Deformity	Apo-Amitriptyline			S	Unknown			Not Reported

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

Apo-Azathioprine	S	Unknown		Not Reported
Apo-Diclofenac	S	Topical		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	7.1429 Milligram Daily;	Not Reported
Etanercept	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S			Not Reported
Misoprostol	S	Unknown		Not Reported
Naprosyn [Naproxen	S	Unknown		Not Reported
Nifedipine	S	Unknown		Not Reported
Orencia	S	Subcutaneous	107.1429 Milligram Daily;	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Winpred	S	Unknown		Not Reported
Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Tofacitinib	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17622559	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217497			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular	80 Milligram Daily;		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17622669	EXPEDITED (15-DAY)		OT	CA-SA-2020SA079660			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Leukopenia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Codeine			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Enbrel			C				Not Reported

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

	Humira			C					Not Reported
	Orencia			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17622915	DIRECT	Y	HO			72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Pancytopenia	Hydroxychloroquine			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623040	DIRECT	Y	OT			78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral				Not Reported
	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623288	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 05347		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction;	Etanercept			S	Unknown	Unknown			Not Reported
Arthralgia; Condition	Actemra			S	Unknown	Unknown			Not Reported
Aggravated; Drug	Apo-Leflunomide			S	Unknown				Not Reported
Ineffective; Joint Swelling;	Arava			S	Unknown	Unknown			Not Reported
Musculoskeletal Disorder;	Enbrel			S	Unknown	Unknown			Not Reported
Neutropenia; Platelet	Orencia			S	Unknown	Unknown			Not Reported
Count Decreased;	Plaquenil			S	Unknown				Not Reported
Sinusitis; Sleep Disorder;	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
Tendon Disorder;	Advil			C	Unknown	Unknown			Not Reported
Thrombocytopenia	Folic Acid			C	Unknown	Unknown			Not Reported

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

Ketorolac	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Naproxen	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown	Unknown	Not Reported
Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623349	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1578		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342132		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Drug Ineffective; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise;	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

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

Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17624098	EXPEDITED (15-DAY)		HO, OT	NVSC2020US090011		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Cardiomyopathy; Cardiotoxicity; Dyspnoea Exertional; Orthopnoea; Peripheral Swelling	Hydroxychloroquine			S	Unknown	200 Unk, Bid		Novartis	
	Prednisone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17624253	EXPEDITED (15-DAY)		OT	CA-EMD SERONO- E2B_90076287		28 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anovulatory Cycle; Bronchitis;	Metformin Hydrochloride			S	Unknown	Unknown		Not Reported	
Dermatomyositis; Drug Ineffective; Gait Inability;	Metformin Hydrochloride			S	Unknown			Not Reported	
Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Intentional Product Use Issue; Joint Range Of	Warfarin Sodium			S	Unknown			Not Reported	
	Cymbalta			S	Unknown	Unknown Dosage		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	
	Plaquenil /00072602/			S	Unknown	Unknown		Not Reported	

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

Motion Decreased; Malaise; Nasopharyngitis; Nausea; Off Label Use; Pain; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder; Weight Increased	Prednisone	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Imuran /00001501/	C	Unknown	Unknown	Not Reported
	Xarelto	C	Unknown	Unknown	Not Reported
	Azathioprine Sodium	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17624589	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-009614			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Desoximetasone			S	Oral			Not Reported
Alopecia; Arthropathy;	Diclofenac Sodium			S	Unknown			Not Reported
Contraindicated Product	Actemra			S	Subcutaneous			Not Reported
Administered; Discomfort;	Alendronate Sodium			S	Oral			Not Reported
Drug Ineffective; Fatigue;	Arava			S	Oral			Not Reported
Glossodynia; Hand	Cetirizine Hydrochloride			S	Unknown			Not Reported
Deformity; Maternal	Cetirizine			S	Unknown			Not Reported
Exposure During	Hydrochloride/Pseudoephedrine							
Pregnancy; Pain;	Hydrochloride							
Pemphigus; Product Use	Cimzia			S	Subcutaneous			Not Reported
Issue; Rash; Rheumatoid	Cortisone Acetate			S	Topical			Not Reported
Arthritis; Swelling;	Enbrel			S	Subcutaneous			Not Reported
Systemic Lupus	Folic Acid			S	Unknown			Not Reported
Erythematous; Wound	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17625486	EXPEDITED (15-DAY)		HO, LT, OT	MX-ACCORD-178039		29 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Abscess;	Mycophenolic Acid			S	Oral			Accord	
Endophthalmitis; Liver Abscess; Muscle Abscess;	Hydroxychloroquine			S	Oral			Not Reported	
Myositis; Nocardiosis; Off Label Use; Perinephric Abscess; Pneumonia; Pyomyositis	Prednisone			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17625490	EXPEDITED (15-DAY)		OT	FR-SUN		54 YR	Female	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

PHARMACEUTICAL
INDUSTRIES LTD-
2020RR-242736

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, In Total		Sun
	Plaquenil			S	Oral	1 Dosage Form, Daily		Not Reported
	Cortancyl 20 Mg, Comprime			S	Oral	()		Not Reported
	Pantoprazole			C	Unknown	()		Not Reported
	Izalgi 500 Mg/25 Mg, Gelule			C	Unknown	()		Not Reported
	Levothyrox 75 Microgrammes, Comprime Secable			C	Unknown	()		Not Reported
	Diffu K, Gelule			C	Unknown	()		Not Reported
	Atorvastatine			C	Unknown	()		Not Reported
	Clopidogrel (Chlorhydrate De)			C	Unknown	()		Not Reported
	Procoralan 5 Mg, Comprime Pellicule			C	Unknown	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2020	16162286	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028- 2733052-00		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Operation; Arthralgia; Contraindicated Product Administered; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2020	17625695	EXPEDITED (15-DAY)		DE	IE-ABBVIE-20K-229-3352301-00		57 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Seroquel			C				Not Reported
	Arava			C				Not Reported
	Depo-Medrone			C				Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Methotrexate			C				Not Reported
	Protium			C				Not Reported
	Valdoxan			C				Not Reported
	Alendronate			C				Not Reported
	Levothyroxine Sodium			C				Not Reported
	Prednisolone			C				Not Reported
	Sulfasalazine			C				Not Reported
	Sulfasalazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2020	17625752	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217530		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported

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

Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	10991568	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20150323608		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diverticulitis; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Swelling; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15066519	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0720		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Sulfasalazine	S		Not Reported
Enbrel	S	Subcutaneous	Not Reported
Apo-Leflunomide	S		Not Reported
Gold	S	Subcutaneous	Not Reported
Ilaris	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15407353	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911920		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Contraindicated Product Administered; Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Pain; Pain In Extremity; Pain In Jaw; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cellcept			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

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

Methotrexate	S	Oral	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Leflunomide	S	Oral	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15620412	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556731-00		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single Use Pre Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Plaquenil			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15625609	EXPEDITED (15-DAY)		DS, HO, OT	CA-ABBVIE-18K-028-2557423-00		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Humira Humira Apo-Cyclosporine Apo-Leflunomide Cimzia Enbrel Enbrel Enbrel Ibuprofen Infliximab Orencia Orencia Otezla Simponi Stelara Alendronate Sodium Apo-Hydroxyquine Codeine Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate			S S S S S S S S S S S S S S S S S S S S S S S S	Subcutaneous Unknown Oral Subcutaneous Unknown Subcutaneous Unknown Oral Oral Subcutaneous Subcutaneous Unknown Subcutaneous Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Not Reported	

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

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Endocervical	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Ibuprofen	S	Oral	Not Reported
Apremilast	S	Unknown	Not Reported
Apremilast	S	Unknown	Not Reported
Apremilast	S		Not Reported
Motrin	S	Oral	Not Reported
Motrin	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Cyclosporine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Ibuprofen	S	Oral	Not Reported
Colchicine	C	Oral	Not Reported
Folic Acid	C		Not Reported
Nitrazepam	C	Oral	Not Reported
Oxycodone	C		Not Reported
Uloric	C		Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported
Benadryl	C		Not Reported
Dexilant	C	Oral	Not Reported
Febuxostat	C		Not Reported
Gravol	C		Not Reported
Mogadon	C	Oral	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15674250	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573605-00			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthrititis; Synovitis; Weight Decreased	Humira			S	Subcutaneous			Not Reported	
	Imuran			S	Unknown			Not Reported	
	Mycophenolate Sodium			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Rituxan			S				Not Reported	
	Acetaminophen			C	Oral			Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Actemra			C				Not Reported	
	Bisoprolol			C				Not Reported	
	Candesartan			C				Not Reported	
	Depo-Medrol			C	Intra-articular			Not Reported	
	Folic Acid			C				Not Reported	
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Sulfamethoxazole/Trimethoprim			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15678194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574920-00		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Colitis; Contraindicated Product Administered; Dental Caries; Diabetes Mellitus	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Diamicron			S	Unknown			Not Reported	
	Gliclazide			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

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Inadequate Control; Drug	Orencia	S	Unknown	Not Reported
Hypersensitivity; Drug	Rituxan	S	Intravenous drip	Not Reported
Ineffective; Drug	Xeljanz	S	Unknown	Not Reported
Intolerance; Gastric	Asacol	S	Unknown	Not Reported
Disorder; Gastrointestinal	Enbrel	S	Subcutaneous 225.0	Not Reported
Disorder; Haematochezia;	Enbrel	S	Subcutaneous	Not Reported
Hypertension; Joint	Enbrel	S	Subcutaneous	Not Reported
Swelling; Musculoskeletal	Enbrel	S	Subcutaneous	Not Reported
Stiffness; Nausea; Oxygen	Enbrel	S	Subcutaneous	Not Reported
Saturation Decreased;	Enbrel	S	Subcutaneous	Not Reported
Pain In Extremity;	Methotrexate	S	Subcutaneous	Not Reported
Peripheral Swelling;	Norvasc	S	Oral	Not Reported
Rheumatoid Arthritis;	Norvasc	S	Oral	Not Reported
Vitamin D Deficiency;	Plaquenil	S	Unknown	Not Reported
Weight Decreased; Weight	Actemra	S	Unknown	Not Reported
Increased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Aerius	C		Not Reported
	Crestor	C		Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Amlodipine Besilate	C	Unknown	Not Reported
	Atacand Plus	C		Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Ebastine	C		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15702726	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2580931-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Humira			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Celebrex			C				Not Reported	
	Lyrica			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15707673	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2584580-00		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Injury; Drug Ineffective; Fall; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not			Not Reported	

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15733752	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594187-00		65 YR	Female	CAN

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

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Hydroxychloroquine Sulfate	C			Not Reported
Xeljanz	C	Unknown		Not Reported
Hydroxychloroquine	C	Ophthalmic		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15734078	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594192-00		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported
Abdominal Pain Upper;	Arava			S	Unknown			Not Reported
Diarrhoea; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Eye Disorder;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Fatigue; Pulmonary Mass;	Methotrexate			S	Oral			Not Reported
Rheumatoid Arthritis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Therapeutic Product Effect	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Decreased; Weight								
Decreased	Sulfasalazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15734387	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594151-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased;	Humira			S	Subcutaneous			Not Reported
Contraindicated Product	Cimzia			S	Subcutaneous			Not Reported
Administered; Drug	Enbrel			S	Subcutaneous			Not Reported
Intolerance; Therapeutic	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Product Effect Decreased	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

		otherwise specified)	
Simponi	S	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Lyrica	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15739251	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2594156-00			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Varilrix			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported

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

Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Subcutaneous	Not Reported
Diclofenac	C	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	15930738	EXPEDITED (15-DAY)	OT		CA-ABBVIE-19K-028-2655654-00		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Metformin Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Topicort			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Altace			C	Unknown			Not Reported
	Asa			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Folic Acid			C	Unknown	1.0		Not Reported
	Methotrexate			C	Oral			Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Vitamin D			C	Unknown			Not Reported
	Docosahexaenoic Acid			C				Not Reported
	Eicosapentaenoic Acid			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16040473	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1020190			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease; Pain; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr	
	Meloxicam			S	Unknown			Teva	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Mobicox			S	Unknown			Not Reported	
	Orencia			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16301153	EXPEDITED (15-DAY)		OT	CA-SA-2019SA121523			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk		Sanofi	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Sanofi	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Lyrica			C	Unknown	Unk		Not Reported	
	Celebrex			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16381114	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2804954-00		51 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amlodipine			C				Not Reported
	Arava			C				Not Reported
	Benadryl			C				Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Viread			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16441274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028- 2822469-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Contraindicated Product Administered; Drug Intolerance; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

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Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Lyrica	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16443280	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2819775-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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

Prednisone	C	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16497972	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019026465			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			S	Endocervical			Not Reported
	Actemra			S				Not Reported
	Arava			S		20 Milligram, Once Daily (Qd)		Not Reported
	Arava			S		10 Milligram, Once Daily (Qd)		Not Reported
	Enbrel			S		50 Milligram, Weekly (Qw)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S		200 Milligram, 2x/Day (Bid)		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	500 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	2000 Milligram, 2x/Day (Bid)		Not Reported
	Sulfasalazine			S	Oral	1000 Milligram, 2x/Day (Bid)		Not Reported
	Methotrexate			C		Unk, Weekly (Qw)		Not Reported

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

Meloxicam	C			Not Reported
Synthroid	C			Not Reported
Acetaminophen And Codeine Phosphate	C			Not Reported
Apo-Prednisone	S	Oral	20 Nanogram	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		200 Milligram, 2x/Day (Bid)	Not Reported
Codeine	C			Not Reported
Tylenol [Paracetamol]	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16714535	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216686			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Celebrex			C				Not Reported
	Lyrica			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	16717736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA216698		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Metals; Arthralgia; Cerebral Disorder; Condition Aggravated; Cystitis;	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Ibuprofen			S	Oral	400 Mg 3-4/Day		Not Reported
	Methotrexate			S		25 Mg, Qw		Not Reported

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Disturbance In Attention; Drug Intolerance; Gait Disturbance; Grip Strength Decreased; Hypersensitivity; Intentional Product Use Issue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Stiffness; Pneumonitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Gold Xeljanz	S S C	Intramuscular Oral	10 Mg, 1x 5 Mg, Bid	Sanofi Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17156996	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20191212448			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematous; Wound	Reactine (Cetirizine Hydrochloride) Reactine (Cetirizine Hydrochloride) Cetirizine Hydrochloride Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride Pseudoephedrine Hydrochloride Remicade Actemra Apo-Prednisone Arava Cimzia Cortisone Acetate Desoximetasone Diclofenac Sodium			S S S S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Intravenous (not otherwise specified) Subcutaneous Unknown Oral Subcutaneous Topical Oral Unknown	 Powder For Solution Intravenous		Johnson And Johnson Johnson And Johnson Johnson And Johnson Johnson And Johnson Johnson And Johnson Janssen Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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

Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified) Solution Intravenous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Janssen
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17173636	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053782			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Cimzia			S	Subcutaneous			Ucb
Alopecia; Arthropathy;	Cetirizine Hydrochloride			S		Unk		Ucb
Contraindicated Product	Cetirizine Hydrochloride			S				Ucb
Administered; Discomfort;	Cetirizine Hydrochloride,			S				Not Reported
Drug Ineffective; Fatigue;	Pseudoephedrine Hydrochloride							
Glossodynia; Hand								

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

Deformity; Maternal	Cetirizine Hydrochloride,	S			Not Reported
Exposure During	Pseudoephedrine Hydrochloride				
Pregnancy; Off Label Use;	Pseudoephedrine Hydrochloride	S			Not Reported
Pain; Pemphigus; Product	Remicade	S	Intravenous (not		Not Reported
Use Issue; Rash;			otherwise specified)		
Rheumatoid Arthritis;	Simponi	S	Subcutaneous		Not Reported
Swelling; Systemic Lupus	Tocilizumab	S	Subcutaneous		Not Reported
Erythematosis; Wound	Apo-Prednisone	S			Not Reported
	Arava	S	Oral		Not Reported
	Arava	S	Oral		Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac Sodium	S			Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram Solution	Ucb
	Hydroxychloroquine	S			Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral	Solution	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not	Unk	Not Reported
			otherwise specified)		
	Phthalylsulfathiazole	S		Unk	Not Reported
	Plaquenil [Hydroxychloroquine	S			Not Reported
	Phosphate]				

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

	Prednisone	S	Oral		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17200098	EXPEDITED (15-DAY)		OT	SE-ADVANSZ PHARMA-201912003018			Unknown	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Cutaneous Lupus Erythematosus; Drug Ineffective	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid ,1 Tablet Twice A Day For 2 Weeks		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form		Concordia
	Tromblyl			C		75 Mg		Not Reported
	Candesartan			C		16 Mg		Not Reported
	Levaxin			C		25 Mg		Not Reported
	Methotrexate			C		Unk		Not Reported
	Dermovate			C		Unk		Not Reported
	Omeprazol			C		Unk		Not Reported
	Rosuvastatin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17350398	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020003181			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported

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

Enbrel	S	50 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Unk	Not Reported
Methotrexate	S	25 Milligram, Weekly (Qw)	Not Reported
Leflunomide	S		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous
Sulfasalazine	S	1 Gram, 2x/Day (Bid)	Not Reported
Hydroxychloroquine Sulfate	S	400 Milligram, Once Daily (Qd)	Not Reported
Xeljanz	C	5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	C	11 Milligram, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17391221	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170826218		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Stelara			S	Subcutaneous			Not Reported
Abdominal Distension;	Simponi			S	Subcutaneous			Janssen
Abdominal Distension;	Remicade			S	Intravenous (not otherwise specified)			Janssen
Adverse Reaction;	Remicade			S	Intravenous (not otherwise specified)			Janssen
Arthralgia; Coeliac Disease; Condition Aggravated;	Enbrel			S	Subcutaneous			Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug-Induced	Sirukumab			S	Unknown			Not Reported
Liver Injury; Dyspepsia; Dyspepsia; Fatigue;	Actemra			S	Subcutaneous			Not Reported
Gastric Disorder; General Physical Health	Arava			S	Oral			Not Reported
Deterioration; Grip Strength Decreased;	Cimzia			S	Subcutaneous			Not Reported
Headache; Hepatic Enzyme Increased;	Humira			S	Subcutaneous			Not Reported
Injection Site Reaction; Insomnia; Joint Swelling; Loss Of Personal	Minocycline			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

Independence In Daily Activities; Malaise;	Xeljanz	S	Oral	Not Reported
Musculoskeletal Stiffness;	Myochrysine	S	Intramuscular	Not Reported
Nail Disorder; Nausea; Off Label Use;	Otezla	S	Oral	Not Reported
Onychomycosis; Pain;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Product Use In Unapproved Indication;	Plaquenil	S		Not Reported
Psoriatic Arthropathy;	Salazopyrin	S	Unknown	Not Reported
Rash; Rheumatoid Arthritis; Sleep Disorder;	Sodium Aurothiomalate	S	Intramuscular	Not Reported
Treatment Failure	Tofacitinib Citrate	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tocilizumab	S		Not Reported
	Orencia	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo Prednison	S	Oral	Not Reported
	Rheumatrex	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17563093	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105863			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Simponi			S	Subcutaneous			Janssen
Adjustment Disorder With Depressed Mood;	Remicade			S	Intravenous (not otherwise specified)			Janssen
Alopecia; Amnesia; Contraindicated Product	Humira			S	Subcutaneous			Not Reported

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

Administered; Delirium;	Humira	S		Not Reported
Diabetes Mellitus;	Methotrexate	S	Unknown	Not Reported
Dislocation Of Vertebra;	Methotrexate	S		Not Reported
Drug Hypersensitivity;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased;	Orencia	S		Not Reported
Gait Disturbance;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Glossodynia; Grip Strength Decreased; Hip Arthroplasty; Infection;	Rituxan	S		Not Reported
Knee Arthroplasty;	Enbrel	S	Subcutaneous	Not Reported
Maternal Exposure During Pregnancy; Mobility Decreased; Muscular Weakness; No Adverse Event; Pain; Pain In Extremity; Pemphigus;	Enbrel	S		Not Reported
Peripheral Swelling;	Cosentyx	S	Unknown	Not Reported
Product Use Issue;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine Sulfate	S		Not Reported
Seronegative Arthritis;	Leflunomide	S	Unknown	Not Reported
Spinal Fusion Surgery;	Sulfasalazine	S	Unknown	Not Reported
Systemic Lupus Erythematosus;	Actemra	S	Unknown	Not Reported
Therapeutic Product Effect Decreased; Walking Aid User; Weight Decreased;	Prednisone	S	Unknown	Not Reported
Wound Infection	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride W/Tri/00005601/	S	Unknown	Not Reported
	Reactine /00884302/	S	Unknown	Not Reported
	Naprosyn /00256201/	C		Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628438	EXPEDITED (15-DAY)		HO	FR-ADVANSZ PHARMA-202003002241			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Fibromyalgia; Malaise; Pleural Effusion	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form,Qd		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628439	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA-202003002041			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence	Hydroxychloroquine			S	Unknown	Unk, (Coated Tablets)		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628622	EXPEDITED (15-DAY)		DS, OT	FR-ADVANSZ PHARMA-202003002294			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiovascular Disorder; Chronic Obstructive Pulmonary Disease; Diabetes Mellitus; Infection; Pneumonia; Respiratory Distress; Wheelchair User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia	
	Cortancyl			C		Unk		Not Reported	
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported	
	Calcium			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628632	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3352546-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628737	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP009312			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Swelling; Rheumatoid Arthritis	Leflunomide			S	Oral	Unk		Apotex	
	Plaquenil /00072602/			S	Oral	Unk		Not Reported	
	Humira			C	Unknown	Unk		Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	
	Simponi			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628958	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014088		82 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Oral Pain; Oropharyngeal Pain; Stomatitis	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, 2x/Day (Bid)		Not Reported	
	Methotrexate			S	Subcutaneous	200 Milligram		Not Reported	
	Benzylhydrochlorothiazide			C				Not Reported	
	Coumadin			C				Not Reported	
	Cyanocobalamin			C				Not Reported	

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

	Eltroxin	C		Not Reported
	Metoprolol	C		Not Reported
	Pravachol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629123	EXPEDITED (15-DAY)		HO, OT	CA-UCBSA-2020014089			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Tocilizumab			S		160 Milligram		Not Reported
	Azathioprine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629213	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA- 202003002163			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthralgia; Condition Aggravated; Systemic Lupus Erythematousus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629297	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1217561			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam	S	Unknown	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629303	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217500		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo- Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Oral			Not Reported

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Synovial Cyst; Synovitis;
Tenosynovitis; Treatment
Failure; Viral Upper
Respiratory Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629306	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217468			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Methotrexate			S	Unknown			Barr	
	Diclofenac Sodium			S	Unknown			Actavis	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Phthalylsulfathiazole			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629352	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217523			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Chemicals;	Meloxicam			S	Unknown			Not Reported
Arthralgia; Bone Density	Leflunomide			S	Unknown			Barr
Decreased; C-Reactive	Methotrexate			S	Unknown			Barr
Protein Increased;	Actemra			S	Subcutaneous			Not Reported
Crepitations; Deformity;	Arava			S	Unknown			Not Reported
Diarrhoea; Dizziness;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Drug Ineffective; Drug	Orencia			S	Unknown			Not Reported
Intolerance; Dry Eye;	Depo-Medrol			C	Unknown			Not Reported
Fatigue; Feeling	Diclofenac			C	Unknown			Not Reported
Abnormal; Fibromyalgia;	Humira			C	Unknown			Not Reported
Hand Deformity; Joint	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
Range Of Motion								
Decreased; Joint Swelling;								
Liver Disorder; Malaise;								
Muscular Weakness;								
Musculoskeletal Pain;								
Musculoskeletal Stiffness;								
Myalgia; Pain In Extremity;								
Peripheral Swelling;								
Pulmonary Toxicity; Rash								
Maculo-Papular; Rash								
Pruritic; Rheumatoid								
Arthritis; Rheumatoid								
Nodule; Synovial Cyst;								
Tenosynovitis; Upper								
Respiratory Tract Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629366	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217536			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug	Meloxicam			S	Oral			Not Reported	
Ineffective; Drug	Actemra			S	Subcutaneous			Not Reported	
Intolerance; Grip Strength									

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Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Arava Enbrel Humira Hydroxychloroquine Sulfate Methotrexate Sulfasalazine	S S S S S C	Unknown Subcutaneous Subcutaneous Unknown Oral Oral	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629396	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217963		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; C- Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin Methotrexate Mycophenolate Mofetil Azathioprine Enbrel Hydroxychloroquine Sulfate Orencia Rituximab Xeljanz Xeljanz			S S S S S S S S C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Intravenous (not otherwise specified) Unknown Unknown			Ivax Barr Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629398	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218003			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic	Ciclosporin Methotrexate			S S	Unknown Subcutaneous			Ivax Barr

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

Fatty Liver Disease; Pruritus; Treatment Failure	Azathioprine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Barr
	Actemra	S	Subcutaneous	23.1429 Milligram Daily;	Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Kevzara	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Magnesium	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629497	EXPEDITED (15-DAY)			US-ADVANS PHARMA- 202003001847			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Height Decreased; Drug Tolerance Increased; Hypoacusis; Joint Injury; Joint Swelling; Migraine; Musculoskeletal Disorder; Therapeutic Product Effect Decreased; Vomiting	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid, One In The Morning One In Night		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629815	EXPEDITED (15-DAY)		OT	MX-ADVANS PHARMA- 202003002043			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Exposure During Pregnancy; Gestational Diabetes; Shortened Cervix	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Oral	200 Mg	Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17630225	EXPEDITED (15-DAY)		OT	NVSC2020CA090993			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased;	Cosentyx			S	Unknown	Unk		Novartis
Contraindicated Product Administered; Diarrhoea;	Leflunomide			S	Unknown	10 Mg, Unknown		Not Reported
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17631124	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3352969-00		71 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis;	Kaletra			S	Oral			Not Reported
Hyperbilirubinaemia; Hypocoagulable State	Hidroxicloroquina			S	Oral	200 Mg/12h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17631943	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217985		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr

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

Methotrexate	S	Oral	Not Reported
Methotrexate	S		Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

10 Milligram Daily;

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318931			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Nausea; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Treatment Failure; Urticaria	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Orencia			S	Subcutaneous			Not Reported

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

Plaquenil /00072602/	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Mefenamic Acid	S	Oral	Not Reported
Gold	S	Unknown	Not Reported
Arthrotec	C	Oral	Not Reported
Tylenol /00020001/	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632057	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217417			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosis; Wound	Alendronate Sodium			S	Oral			Actavis
	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Intra-arterial	25 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Oral			Actavis
	Prednisone			S	Unknown			Actavis
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride							
	Cimzia			S	Subcutaneous			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cortisone Acetate			S	Topical			Not Reported

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

	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632099	NON-EXPEDITED		OT	NVSC2020US092034		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiomyopathy; Diastolic Dysfunction	Hydroxychloroquine			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632120	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217560			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg		Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S		20 Millimol Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

Methotrexate	S	Oral	Not Reported
Sulfasalazine	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632164	EXPEDITED (15-DAY)		OT	NVSC2020FR079225		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acarodermatitis; Ocular Toxicity	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632212	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014049		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Azathioprine			S				Not Reported
	Arava			S		Unk		Not Reported
	Azathioprine			S				Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sodium Aurothiomalate			S				Not Reported
Cephalexin Monohydrate			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632213	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014044		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Increased; Cataract;	Cimzia			S	Subcutaneous			Not Reported
Diarrhoea; Drug	Desoximetasone			S				Not Reported
Hypersensitivity; Drug	Enbrel			S	Subcutaneous	1 Dosage Form, Weekly (Qw)		Not Reported
Ineffective; Drug								
Intolerance; Eye Disorder;	Glumetza			S		500 Milligram, 2x/Day (Bid)		Not Reported
Glaucoma; Hernia; Herpes								
Zoster; Insomnia; Joint	Humira			S	Subcutaneous			Not Reported
Swelling; Loss Of								
Personal Independence In	Hydroxychloroquine			S				Not Reported
Daily Activities;	Hydroxychloroquine Sulfate			S				Not Reported
Nasopharyngitis; Off Label	Lyrica			S	Oral			Not Reported
Use; Pain In Extremity;	Methotrexate			S				Not Reported
Peripheral Swelling;	Methotrexate			S	Oral			Not Reported
Therapeutic Product Effect								
Decreased	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Acetaminophen			C				Not Reported
	Altace			C				Not Reported
	Arava			C				Not Reported
	Asa			C				Not Reported
	Codeine			C				Not Reported
	D-Alpha Tocopherol			C				Not Reported
	Ergocalciferol			C				Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported

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

Rosuvastatin Calcium				C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217430			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Diclofenac Sodium			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Phthalylsulfathiazole			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632341	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217513			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling;	Meloxicam			S	Oral			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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

Pain In Extremity;	Humira	S	Subcutaneous	Not Reported
Peripheral Swelling;	Methotrexate	S	Oral	Not Reported
Therapeutic Product Effect	Arava	S	Unknown	20 Milligram Daily;
Decreased; Treatment	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Failure	Sulfasalazine	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632490	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-2014318US			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Epistaxis;	Risedronate Sodium Unk			S	Oral	35 Mg, Q Week		Allergan
Headache; Insomnia;	Arava			S	Oral	20 Mg, Qd		Not Reported
Nausea; Osteonecrosis Of	Mycophenolate Mofetil			S	Oral	500 Mg, Bid		Not Reported
Jaw; Transaminases	Mycophenolate Mofetil			S	Oral	1 G, Bid		Not Reported
Increased	Plaquenil			S	Unknown	300 Mg, Qd		Not Reported
	Azathioprine			C	Oral	50 Mg, Qd		Not Reported
	Azathioprine			C	Oral	150 Mg, Qd		Not Reported
	Azathioprine			C	Oral	100 Mg, Bid		Not Reported
	Humira			C	Subcutaneous	40 Mg, Q2weeks		Not Reported
	Ketoprofen			C	Unknown	Unk		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported
	Methotrexate			C	Subcutaneous	25 Mg, Q Week		Not Reported
	Prolia			C	Subcutaneous	Actual: 60 Mg, Every 6 Months		Not Reported
	Rituximab			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632612	EXPEDITED (15-DAY)		OT	CA-SA-2020SA073892			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Leflunomide Hydroxychloroquine Methotrexate Sulfasalazine	S S S S	Sanofi Sanofi Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632859	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217558			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam Actemra Arava Enbrel Humira Hydroxychloroquine Sulfate Methotrexate Sulfasalazine			S S S S S S S C	Oral Subcutaneous Unknown Subcutaneous Subcutaneous Unknown Oral Oral	20 Milligram Daily; 2.8571 Milligram Daily;		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17633310	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217525		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular	Meloxicam Leflunomide Methotrexate Actemra Gold Humira Hydroxychloroquine Sulfate Orencia			S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown	22.8571 Milligram Daily;		Not Reported Barr Barr Not Reported Not Reported Not Reported Not Reported Not Reported

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

Weakness;	Depo-Medrol	C	Other	Not Reported
Musculoskeletal Pain;	Diclofenac	C	Unknown	Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Myalgia; Pain; Pain In	Pantoprazole Magnesium	C	Unknown	Not Reported
Extremity; Peripheral	Prednisone	C	Unknown	Not Reported
Swelling; Pulmonary	Xeljanz	C	Oral	Not Reported
Toxicity; Rash Maculo-				
Papular; Rash Pruritic;				
Rheumatoid Arthritis;				
Rheumatoid Lung;				
Synovial Cyst; Synovitis;				
Tenosynovitis; Viral Upper				
Respiratory Tract Infection				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17633436	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217998			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Ciclosporin			S	Unknown			Ivax
Blood Creatinine	Methotrexate			S	Unknown			Barr
Increased; Drug	Actemra			S	Unknown			Not Reported
Hypersensitivity; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Drug	Humira			S	Subcutaneous			Not Reported
Intolerance; Mobility	Orencia			S	Unknown			Not Reported
Decreased;	Rituximab			S	Intravenous (not			Not Reported
Musculoskeletal Pain;					otherwise specified)			
Neck Pain; Pain In	Sulfasalazine			S	Unknown			Not Reported
Extremity; Pain In Jaw;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Rheumatoid Arthritis	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Tylenol Arthritis Pain 8h			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17633463	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217508			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Meloxicam			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown	200 Milligram Daily;		Not Reported
	Actemra			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17633465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217531			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain;	Meloxicam			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol			C				Not Reported
	Diclofenac			C				Not Reported
	Humira			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Musculoskeletal Stiffness;
Myalgia; Pain In Extremity;
Peripheral Swelling;
Pulmonary Toxicity; Rash
Maculo-Papular; Rash
Pruritic; Rheumatoid
Arthritis; Rheumatoid
Nodule; Synovial Cyst;
Tenosynovitis; Upper
Respiratory Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17633498	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160217144			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Carpal Tunnel Syndrome; Drug Ineffective; Hip Fracture; Intervertebral Disc Disorder; Nausea; Rheumatoid Arthritis; Stress Fracture; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	14299100	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2017050873			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Ankle Arthroplasty; Contraindicated Product Administered; Drug Ineffective; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Cimzia	S	Subcutaneous	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Anakinra	S		Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Gold	S		Unk	Not Reported
	Plaquenil	S	Oral		Not Reported
	Methotrexate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	15624086	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2557445-00		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cellcept			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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

Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	15679987	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2573622-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Indometacin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

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

Statex (Morphine Sulfate)	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	C		Not Reported
Prednisone	C	Unknown	Not Reported
Statex	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	15711682	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587778-00		52 YR	Female	CAN

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

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

Plaquenil			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	16182582	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2738227-00		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Humira			S	Subcutaneous			Not Reported	
Deformity; Drug	Levothyroxine			S	Unknown			Not Reported	
Ineffective; Dyspnoea;	Levothyroxine			S	Subcutaneous			Not Reported	
Gait Disturbance; Hand	Dorzolamide			S	Ophthalmic			Not Reported	
Deformity; Injection Site	Hydrochloride/Timolol Maleate								
Reaction; Mobility	Folic Acid			S	Unknown			Not Reported	
Decreased; Off Label Use;	Hydroxychloroquine			S	Unknown			Not Reported	
Pain; Product Use Issue;	Methotrexate			S	Subcutaneous			Not Reported	
Rheumatoid Arthritis;	Prednisone			S	Unknown			Not Reported	
Sciatica	Ramipril			S	Unknown			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Apo-Ramipril			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Codeine Phosphate			S	Unknown			Not Reported	
	Cosopt			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Levothyroxine Sodium			S	Unknown			Not Reported	

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

Altace	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Intravenous (not otherwise specified)	Not Reported
Tylenol No.2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C		Not Reported
Acetaminophen/Caffeine/Codeine Phosphate	C		Not Reported
Caffeine W/Dihydrocodeine Bitartrate/Paracetamol	C		Not Reported
Caffeine	C		Not Reported
Dorzolamide Hydrochloride/Timololmaleate	C	Ophthalmic	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	16805717	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2921109-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Psoriatic Arthropathy	Humira			S	Subcutaneous			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Stelara			S	Subcutaneous			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous drip			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Otezla			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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

Leflunomide	C		Not Reported
Methotrexate	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17257461	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020AU004219			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Mycophenolate Mofetil			S	Oral	500 Mg, Tid		Novartis
Ageusia; Arthralgia;	Mycophenolate Mofetil			S				Novartis
Depression; Dna Antibody	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
Negative; Drug Interaction;	Methotrexate			S	Subcutaneous	10 Mg, Biw		Not Reported
Fibromyalgia; Gait	Methotrexate			S	Subcutaneous	10 Unk, Biw (Mcg)		Not Reported
Disturbance; Liver	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
Function Test Abnormal;	Methotrexate			S	Subcutaneous	10 Mg		Not Reported
Migraine; Nausea; Panic	Rosuvastatin			S	Unknown	10 Mg		Not Reported
Attack; Paraesthesia;	Ezetimibe			S	Unknown	10 Mg		Not Reported
Psoriasis; Psoriatic	Ramipril			S	Unknown	Unk Mg, Unknown (5-10)		Not Reported
Arthropathy; Respiratory	Topiramate			S	Unknown	200 Mg, Unknown		Not Reported
Syncytial Virus Infection;	Leflunomide			S	Unknown	Unk		Not Reported
Sleep Disorder; Suicidal	Paracetamol			S	Unknown	Unk		Not Reported
Ideation; Systemic Lupus	5-Methyltetrahydrofolate			S	Unknown	Unk		Not Reported
Erythematosis;	Oxycontin			S	Oral	10 Mg, Bid		Not Reported
Tachyarrhythmia; Type 1	Endone			S	Oral	5 Mg, Qd		Not Reported
Diabetes Mellitus; Urinary	Aspirin			S	Unknown	100 Mg, Unknown		Not Reported
Tract Infection; Viral	Prasugrel			S	Unknown	10 Mg, Qd		Not Reported
Tonsillitis	Ivabradine			S	Unknown	7.5 Mg, Bid		Not Reported
	Sildenafil			S	Oral	12.5 Mg, Prn		Not Reported
	Gtn			S	Oral	Unk		Not Reported
	Cannabis Sativa Oil			S	Unknown	Unk		Not Reported
	Reboxetine			S	Unknown	4 Mg, Bid		Not Reported

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	Cholecalciferol	S	Unknown	50 Unk, Qd (Mcg)	Not Reported
	Novorapid	S	Subcutaneous	Unk (Pump With Continuous Bgl Monitor)	Not Reported
	Glucagen Hypokit	S	Unknown	Unk	Not Reported
	Mirena	S	Unknown	52 Mg, Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Biw	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17374357	NON-EXPEDITED			US-PFIZER INC-2020048790		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17394735	EXPEDITED (15-DAY)		OT	RU-ADVANS PHARMA-202002000642			Unknown	RUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd (Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	2 Dosage Form, Qd (Tablet) (Increased The Dose)		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17557550	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318948		72 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Fibromyalgia; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Plaquenil /00072602/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17557559	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318949			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Pms		Not Reported
	Benadryl /00000402/			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Demerol			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran /00001501/			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib Citrate			S	Oral			Not Reported

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Ezetrol			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17557586	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318928		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17558039	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318940			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Oxycodone Terephthalate			C	Unknown			Not Reported	
	Percocet /00446701/			C	Unknown			Not Reported	
	Thiamine Hydrochloride			C	Unknown			Not Reported	
	Acetaminophen W/Oxycodone			C	Unknown			Not Reported	

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Hydrochloride			
Acetaminophen	C	Unknown	Not Reported
Oxycodone Terephthalate	C	Unknown	Not Reported
Acetaminophen W/Oxycodone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17566305	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320978			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Duration- 730 And 731		Not Reported

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(Unspecified Units)									
	Enbrel	S	Unknown						Not Reported
	Enbrel	S	Unknown						Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown						Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown						Not Reported
	Diclofenac Sodium And Misoprostol	S	Unknown						Not Reported
	Cimzia	S	Unknown						Not Reported
	Cimzia	S	Subcutaneous						Not Reported
	Arava	S	Unknown						Not Reported
	Arava	S	Unknown						Not Reported
	Leflunomide	S	Unknown						Not Reported
	Leflunomide	S	Unknown						Not Reported
	Actemra	S	Unknown						Not Reported
	Vitamin D3	C	Unknown						Not Reported
	Imuran /00001501/	C	Unknown						Not Reported
	Gold	C	Unknown						Not Reported
	Arthrotec	C	Unknown						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17566309	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320884		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Disorder; Knee	Orencia	S	Unknown	Not Reported
Arthroplasty; Mobility	Prednisone	S	Unknown	Not Reported
Decreased;	Prednisone	S	Unknown	Not Reported
Musculoskeletal	Actemra	S	Unknown	Not Reported
Discomfort; Nausea; Pain;	Apo Leflunomide	S	Unknown	Not Reported
Rheumatoid Arthritis;	Apo-Prednisone	S	Unknown	Not Reported
Stress Fracture; Vomiting;	Enbrel	S	Unknown	Not Reported
Wrist Deformity	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil /00072602/	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17575971	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP008932		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Q.O.Wk.		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Cyclical		Not Reported

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Orencia	S	Subcutaneous	250 Mg, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	25 Unk, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk (1 Every 6 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Unk, Cyclical	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
Salazopyrin	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Arava	C	Oral	10 Mg, Unk	Not Reported
Bifidobacterium Bifidum	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	40 Mg, Unk	Not Reported
Prednisone	C	Unknown	250 Mg, Unk	Not Reported
Simponi	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk	Not Reported
Wellbutrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported

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Xeljanz			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17577750	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200320438		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S				Not Reported	
	Methotrexate			S				Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Lyrica			C				Not Reported	
	Prednisone			C	Oral			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17596897	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068369		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi	
	Leflunomide			S		Unk		Sanofi	
	Hydroxychloroquine			S		Unk		Sanofi	
	Hydroxychloroquine Sulfate			S		Unk		Sanofi	
	Methotrexate			S		Unk		Not Reported	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	

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Orencia	S	Unk	Not Reported
Plaquenil	S	Unk	Sanofi
Remicade	S	Intravenous (not otherwise specified) Powder For Solution Intravenous	Not Reported
Rituximab	S	Intravenous (not otherwise specified) Unk	Not Reported
Humira	S	Subcutaneous 40 Mg Solution	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17596961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068453			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Arava			S		Unk		Sanofi
	Prednisone			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cortisone Acetate			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S		Unk		Not Reported
	Actemra			S				Not Reported
	Remicade			S	Intravenous (not	Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17597473	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068824		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Shoulder Operation; Therapeutic Response Decreased	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Methotrexate			S				Not Reported
	Orencia			S				Not Reported
	Sulfasalazine			S				Not Reported
	Cymbalta			C				Not Reported
	Hydromorphone			C				Not Reported
	Hydromorph Contin			C				Not Reported
Lyrica			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17597488	EXPEDITED (15-DAY)		OT	CA-SA-2020SA068873		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	5 Mg		Sanofi
	Methotrexate			S	Unknown	5 Mg		Not Reported
	Cimzia			S	Subcutaneous	200 Mg		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown			Not Reported

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	Xeljanz		S	Oral	5 Mg, Bid			Not Reported	
	Prednisone		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17608427	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009050			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hepatitis; Hypersensitivity; Inflammatory Marker Increased; Keratitis; Off Label Use; Skin Reaction; Synovitis; Thyroid Cancer	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Endocervical	Unk		Apotex	
	Orencia			S	Unknown	Unk		Not Reported	
	Xeljanz			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported	
	Etanercept			S	Unknown	50 Mg, Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Aspirin /00002701/			C	Unknown	Unk		Not Reported	
	Avapro			C	Unknown	Unk		Not Reported	
	Biaxin			C	Unknown	Unk		Not Reported	
	Humalog			C	Unknown	Unk		Not Reported	
	Insulin			C	Oral	Unk		Not Reported	
	Lantus			C	Unknown	Unk		Not Reported	
	Metformin Hydrochloride			C	Unknown	Unk		Not Reported	
	Nystatin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17608759	EXPEDITED (15-DAY)		OT	IT-ADVANSZ PHARMA-202002001099			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Platelet Count	Hydroxychloroquine Sulfate			S	Unknown	Unk		Concordia	

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Decreased; Red Blood Cell Count Decreased; Visual Impairment	(Authorized Generic),Plaquenil Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil Imiquimod	S					Concordia
		C		Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17635250	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014082		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S		25 Milligram, Once Daily (Qd)		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17635999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218958			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug	Ciclosporin			S	Unknown			Ivax
	Methotrexate			S	Unknown			Barr

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

Intolerance; Rheumatoid Arthritis	Azathioprine	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17636247	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000018			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Contraindicated Product Administered; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Panacea Biotec
	Hydroxychloroquine			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Ramipril			S	Transplacental			Not Reported
	Simvastatin			S	Transplacental			Not Reported
	Pantoprazole			S	Transplacental			Not Reported
	Metamizole Sodium			S	Transplacental			Not Reported
	Nicotine			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Aliskiren			S	Transplacental			Not Reported
	Torsemide			S	Transplacental			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported

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

Xarelto	S	Transplacental	Not Reported
Ezetimibe	S	Transplacental	Not Reported
Prednisolone	S	Transplacental	Not Reported
Dalteparin Sodium	S	Unknown	Not Reported
Acetylsalicylic Acid	S	Transplacental	Not Reported
Acetylsalicylic Acid	S	Transplacental	Not Reported
Acetylsalicylic Acid	S	Transplacental	Not Reported
Novaminsulfon	S	Transplacental	Not Reported
Novaminsulfon	S	Transplacental	Not Reported
Torasemide	S	Transplacental	Not Reported
Rituximab	S	Transplacental	Not Reported
Enoxaparin Sodium	S	Transplacental	Not Reported
Misoprostol	C	Transplacental	Not Reported
Ramipril	S	Transplacental	Not Reported
Enoxaparin Sodium	C	Transplacental	Not Reported
Advagraf	S	Transplacental	Not Reported
Advagraf	S	Transplacental	Not Reported
Advagraf	S	Transplacental	Not Reported
Mifegyne	C	Transplacental	Not Reported
Cyclophosphamide	C	Transplacental	Not Reported
Heparin	S	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17636295	EXPEDITED (15-DAY)		LT	NVSC2020US090949			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Near Death Experience	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
	Benadryl			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

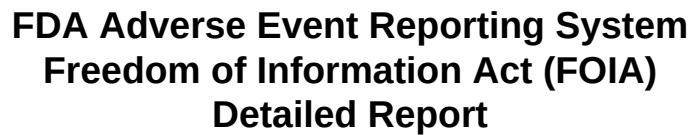
Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17636540	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219972		54 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	20 Mg		Teva	
	Hidroxicloroquina (2143a)			S	Oral	400mg/12h Dia 1 Seguido De 200mg/12h		Teva	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17636766	EXPEDITED (15-DAY)		OT	CA-SA-2020SA085603			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Topicort			S	Topical			Sanofi	
	Hydroxychloroquine Sulfate			S				Sanofi	
	Arava			S				Sanofi	
	Methotrexate			S				Not Reported	
	Folic Acid			S	Subcutaneous	1 Mg		Not Reported	
	Prednisone			S				Not Reported	
	Alendronate Sodium			S				Not Reported	
	Cetirizine Hydrochloride			S				Not Reported	
	Actemra			S				Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S				Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17637797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029039		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	



<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17637833	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219073		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax	
	Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17638187	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1219970		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400mg / 12h Day 1 Followed By 200mg / 12h		Teva	
	Hidroxicloroquina (2143a)			S	Oral			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17638596	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS-2020GMK047124			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbycusis; Renal Impairment; Skin Lesion; Treatment Failure	Gabapentin			S	Unknown	100 Milligram, Bid		Glenmark	
	Actemra			S	Intravenous (not otherwise specified)	488 Milligram; 1 Every 1 Month		Not Reported	
	Arava			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Not Reported	
	Fentanyl			S	Unknown	Unk		Not Reported	
	Oxycontin			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	2.5 Gram, Qd		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Myochrysine			S	Intramuscular	50 Milligram, 1 Every 3 Week		Not Reported	
	Myochrysine			S	Intramuscular	50 Milligram; 1 Every 3 Weeks		Not Reported	
	Methotrexate			S	Subcutaneous	Unk, Qw (1 Every 1 Week)		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
	Enbrel			S	Unknown	50 Milligram, Qw (1 Every 1 Week)		Not Reported	
	Aclasta			C	Intravenous (not	750 Milligram, 1 Every 1		Not Reported	

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		otherwise specified)	Month	
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid (2 Every 1 Day)	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk, Od	Not Reported
Ergocalciferol	C	Unknown	Unk, Od (1 Every 1 Day)	Not Reported
Ergocalciferol	C	Unknown	400 Iu International Unit(S), Qd	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid (2 Every 1 Day)	Not Reported
Ferrous Fumarate	C	Unknown	300 Milligram, Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hydroxocobalamin	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram, Unk	Not Reported
Nasonex	C	Unknown	2 Dosage Form, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	40 Milligram, Od	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram, Unk	Not Reported
Prednisone	C	Unknown	5.0 Gigabecquerel, Od	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qw (1 Every 1 Week)	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Od	Not Reported
Tylenol /00020001/	C	Unknown	1000 Milligram, Qd	Not Reported

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Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17638618	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219130			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17638636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1219180		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr

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Actemra	S	Intravenous (not otherwise specified)	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Neoral	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported

10 Milligram Daily;

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17638655	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218933		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17638683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1218942		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Overlap Syndrome; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17639284	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-202003002713			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Drug Ineffective; Hepatic Fibrosis; Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17639471	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001059			Unknown	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Cardiomyopathy; Cutaneous Lupus Erythematosis; Neutropenia; Renal Failure; Retinal Injury; Thrombocytopenia; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	300 Milligram, Qd		Ipca	
	Hydroxychloroquine			S	Unknown	Unk		Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17641570	EXPEDITED (15-DAY)		OT	NVSC2020US094182		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiotoxicity; Product Use In Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17641778	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-028981			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
Remicade			S	Intravenous (not otherwise specified)			Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	12736125	NON-EXPEDITED			US-PFIZER INC-2016421350		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Animal Scratch; Impaired Healing; Therapeutic Product Effect Incomplete	Xeljanz			S		5 Mg, Unk		Pfizer	
	Xeljanz			S		10 Mg, Unk		Pfizer	
	Xeljanz			S		5 Mg, Unk		Pfizer	
	Hydroxychloroquine			S		200 Mg, Unk		Not Reported	
	Duloxetine			S		30 Mg, Unk		Not Reported	
	Vitamin D2			S		50000 Iu, Weekly		Not Reported	
	Alendronate			S		70 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	13519393	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038017		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Orencia			S	Unknown	750 Mg		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg, Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Gold			S	Unknown	50 Mg, Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	

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

Apo-Leflunomide	S	Oral	20 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	400 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	20 Milligram	Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported
Leflunomide	S	Oral	20 Milligram	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
Meloxicam	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	13676502	EXPEDITED (15-DAY)		OT	CA-TEVA-780631ACC		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Actonel			S	Unknown			Teva
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Methotrexate Sodium			S	Subcutaneous			Barr
	Methotrexate Sodium			S	Subcutaneous			Barr
	Risedronic Sodium			S	Unknown			Teva
	Risedronic Sodium			S	Oral			Teva
	Risedronic Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

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

Arthritis; Rheumatoid Factor Positive; Synovitis	Humira	S	Subcutaneous		Not Reported
	Plaquenil	S	Unknown	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Plaquenil	S	Oral	300 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	1 Dosage Forms Daily;	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram Daily;	Not Reported
	Apo-Risedronate	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15621982	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557440-00		42 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased	Humira	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15623808	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555897-00		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Unevaluable Event	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Minocycline			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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

	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Amoxicillin Sodium And Clavulanate Potassium	C	Unknown	Not Reported
	Amoxil	C	Unknown	Not Reported
	Clavulin	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Bcg	C	Intravesical	Not Reported
	Bcg	C	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Amoxicillin Trihydrate And Clavulanate Potass	C		Not Reported
	Risedronate	C	Oral	Not Reported
	Amoxicillin And Clavulanate Potassium	C	Unknown	Not Reported
	Adalimumab	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15630623	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556317-00		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein	Humira			S	Subcutaneous			Not Reported

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

Abnormal; Contraindicated Product Administered; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15651514	EXPEDITED (15-DAY)		DS, LT, OT	CA-GLAXOSMITHKLINE-CA2015187246			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Blister; Condition Aggravated; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health	Cetirizine Hydrochloride			S		10 Mg, Unk		Glaxosmithkline	
	Cetirizine Hydrochloride			S		Unk		Glaxosmithkline	
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily (Qd)		Glaxosmithkline	
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Glaxosmithkline	
	Cetirizine Hydrochloride			S		Unk		Glaxosmithkline	
	Zyrtec-D			S		10 Mg, Unk		Glaxosmithkline	
	Zyrtec-D			S				Glaxosmithkline	
	Cirrus			S		Unk		Glaxosmithkline	
	Cetirizine Hydrochloride			S	Oral	10 Milligram, Once Daily		Glaxosmithkline	

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

Deterioration;				(Qd)	
Glossodynia; Hand	Cetirizine Hydrochloride	S			Glaxosmithkline
Deformity; Helicobacter	Folic Acid	S		5 Mg, Unk	Glaxosmithkline
Infection; Hepatic Enzyme	Folic Acid	S		5 Milligram	Glaxosmithkline
Increased;	Folic Acid	S		1 Milligram	Glaxosmithkline
Hypersensitivity; Infusion	Folic Acid	S		1 Mg	Glaxosmithkline
Related Reaction; Injury;	Folic Acid	S			Glaxosmithkline
Intentional Product Use	Desoximetasone	S	Oral	Unk	Glaxosmithkline
Issue; Joint Swelling;	Desoximetasone	S	Oral	Unk	Glaxosmithkline
Maternal Exposure During	Pseudoephedrine Hydrochloride	S		Unk	Glaxosmithkline
Pregnancy; Off Label Use;	Pseudoephedrine Hydrochloride	S		1 Milligram	Glaxosmithkline
Pain; Pemphigus;	Pseudoephedrine Hydrochloride	S		25 Milligram	Glaxosmithkline
Pericarditis; Product Use	Pseudoephedrine Hydrochloride	S		10 Milligram	Glaxosmithkline
Issue; Rash; Rheumatoid	Diclofenac Sodium	S		Unk	Glaxosmithkline
Arthritis; Swelling;	Paracetamol	S		Unk	Glaxosmithkline
Synovitis; Systemic Lupus	Cortisone Acetate	S	Topical	25 Milligram	Glaxosmithkline
Erythematosis; Treatment	Diclofenac	S		Unk	Glaxosmithkline
Failure; Wound	Topicort	S	Cutaneous	Unk	Glaxosmithkline
	Cetirizine Hydrochloride +	S		Controlled Release	Not Reported
	Pseudoephedrine Hydrochloride			Tablets	
	Cetirizine Hydrochloride +	S		25 Milligram, Ointment	Not Reported
	Pseudoephedrine Hydrochloride				
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Cimzia	S			Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Sulfathalidine	S		Dosage Form: Unspecified	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Mg	Not Reported

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

Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, Once Daily (Qd)	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Sulfasalazine	S		Unk	Not Reported
Apo-Folic Acid	S		5 Mg, Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		1 Milligram	Not Reported
Apo-Prednisone	S		5 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported

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

Xeljanz	S		5 Mg, 2x/Day (Bid)	Not Reported
Stelara	S		Unk	Not Reported
Prednisone	S	Oral	Dosage Form: Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Sarilumab	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Glaxosmithkline
Simponi	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg (0.8 MI)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Milligram	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

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

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Once Daily (Qd)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	Unk Unk, 2x/Day (Bid)	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	Unk Unk, Once Daily (Qd)	Not Reported
Plaquenil	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Salazopyrin	C		Unk	Not Reported
Atasol (Acetaminophen)	C		Unk	Not Reported
Tofacitinib Citrate	C		Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk Unk, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
Adalimumab	S		Unk	Not Reported
Golimumab	S		Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Desoximetasone	S	Oral	Cutaneous Route	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15664903	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2571352-00			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Humira			S	Subcutaneous			Not Reported	
	Apo-Hydroxyquine			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15712495	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2587774-00		55 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	15738004	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2595168-00		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Meloxicam	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	16575509	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2852070-00		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Diclofenac Sodium/Misoprostol			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Vitamin D3			C				Not Reported
	Ergocalciferol			C				Not Reported
	Colecalciferol			C				Not Reported
Imuran			C				Not Reported	
Gold			C				Not Reported	
Arthrotec			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	16864058	EXPEDITED (15-DAY)		OT	DE-GILEAD-2019-0424518			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema	Ambrisentan	S	Unknown	Unk	Gilead
Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Roactemra	S	Unknown	162 Mg, Z(Weekly)	Not Reported
	Quensyl	S	Unknown	20 Mg, Bid	Not Reported
	Ramipril	S	Unknown	2.5 Mg, Bid	Not Reported
	Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
	Eliquis	S	Unknown	2.5 Mg, Bid	Not Reported
	Eliquis	S	Unknown	1 Dosage Form	Not Reported
	Omeprazole	S	Unknown	20 Mg, Bid	Not Reported
	Lyrica	C	Unknown	100 Mg, Tid	Not Reported
	Pregabalin	S	Unknown	100 Mg, Tid	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	16991114	EXPEDITED (15-DAY)		OT	CA-SA-2019SA303996			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Desoximetasone			S	Oral			Sanofi
Alopecia; Arthropathy;	Diclofenac Sodium			S				Not Reported
Contraindicated Product Administered; Discomfort;	Prednisone			S	Oral			Not Reported
Drug Ineffective; Fatigue;	Prednisone			S				Not Reported
Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain;	Arava			S	Oral			Sanofi
Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling;	Cetirizine Hydrochloride			S				Not Reported
Systemic Lupus	Cetirizine			S				Not Reported
Erythematous; Wound	Hydrochloride/Pseudoephedrine Hydrochloride							
	Folic Acid			S		1 Mg		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Hydroxychloroquine			S				Sanofi
	Methotrexate			S	Intra-arterial	25 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil			S				Sanofi

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

Pseudoephedrine Hydrochloride	S					Sanofi
Sulfasalazine	S	500 Mg				Not Reported
Cimzia	S	Subcutaneous				Not Reported
Actemra	S	Subcutaneous				Not Reported
Cortisone Acetate	S	Topical	25 Mg			Not Reported
Enbrel	S	Subcutaneous				Not Reported
Humira	S	Subcutaneous	40 Mg			Not Reported
Methotrexate Sodium	S					Not Reported
Orencia	S	Intravenous (not otherwise specified)				Not Reported
Orencia	S	Subcutaneous	Unk			Not Reported
Phthalylsulfathiazole	S					Not Reported
Remicade	S	Intravenous (not otherwise specified)				Not Reported
Rituxan	S	Intravenous (not otherwise specified)				Not Reported
Simponi	S					Not Reported
Apo Prednison	S					Not Reported
Xeljanz	C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17405411	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-008376		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Lyrica			S	Oral			Not Reported	

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

	Methotrexate	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17579771	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327850		27 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17579774	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327867		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Unevaluable	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Prednisone			S	Oral			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	

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

Event; Urinary Tract Infection	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Tofacitinib	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17583352	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024371		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Pregabalin			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab;Vorhyaluronidase Alfa			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported

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

Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Piroxicam	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17587303	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329619			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Prednisone			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17587307	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327870		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Ineffective; Gastric Ulcer; Gastrointestinal Disorder; Haemoptysis; Peptic Ulcer	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17605637	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333273		52 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Gait Inability; Inflammatory Marker Increased; Pain In Extremity; Sleep Disorder Due To A General Medical Condition	Simponi			S	Subcutaneous			Janssen	
	Otezla			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17605638	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333296		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Simponi			S	Subcutaneous			Janssen	
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported	
	Enbrel			S	Unknown	1.0 Dosage Forms		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			C	Oral			Not Reported	
	Codeine Phosphate			C	Unknown			Not Reported	
	Lyrica			C	Oral			Not Reported	
	Tylenol			C	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17641623	EXPEDITED (15-DAY)		HO, OT	EG-ADVANZ PHARMA-202003002270			Unknown	EGY
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Blindness; Blood Glucose Abnormal; Brain Oedema; Loss Of Consciousness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia	
	Insulin			C		30 lu, Qd		Not Reported	
	Menthol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17642134	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202003002077			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hip Surgery; Pain	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17642991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029406		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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	Rituximab		S	Intravenous (not otherwise specified)				Not Reported	
	Sulfasalazine		S	Unknown				Not Reported	
	Naproxen		C	Unknown	500 Milligram, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17644154	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1220064		40 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Hydroxicloroquina (2143a)			S	Oral	400 Mg / 12 Day 1 Followed By 200 Mg / 12h		Teva	
	Hydroxicloroquina (2143a)			S	Oral			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17644417	EXPEDITED (15-DAY)		DE, OT	US-ADVANSZ PHARMA-202003002359			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17645665	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1655		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity;	Anakinra			S	Subcutaneous			Not Reported	
	Actemra			S				Not Reported	
	Arava			S	Oral			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S	Oral			Not Reported	
	Azathioprine Sodium			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Etanercept	S	Subcutaneous	Not Reported
	Gold	S	Intramuscular	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Penicillamine	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Docusate Sodium	C	Oral	Not Reported
	Elavil	C	Unknown	Not Reported
	Tobramycin	C	Unknown	0.3% 4x1 Daily Not Reported
	Cyclophosphamide	C	Intravenous (not otherwise specified)	Not Reported
	Doxycycline	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Sulfasalazine	C	Oral	1.5 G 2x1 Daily Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

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08-Apr-2020	17645724	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009359			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nephrotic Syndrome	Prednisone			S	Oral	Unk		Not Reported	
	Mycophenolate			S	Unknown	Unk		Novartis	
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Imuran /00001501/			S	Unknown	Unk		Not Reported	
	Cellcept /01275102/			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17645727	NON-EXPEDITED			NVSC2020US094449		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown	Unk		Novartis	
	Rituximab			S	Unknown	Unk		Not Reported	
	Minocycline			S	Unknown	Unk		Not Reported	
	Colchicine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17646286	EXPEDITED (15-DAY)		DE, OT	US-ADVANSZ PHARMA-202003002360			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	

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08-Apr-2020	17646292	EXPEDITED (15-DAY)		DE, OT	US-ADVANS PHARMA-202003002361			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17646454	EXPEDITED (15-DAY)		OT	FR-ADVANS PHARMA-202003002357			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Off Label Use; Prostatic Adenoma	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd (Film-Coated Tablet)		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17646991	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-028979		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; C-Reactive Protein	Orencia			S	Unknown			Bristol Myers Squibb	
Abnormal; Chest Pain;	Azathioprine			S	Unknown			Not Reported	
Drug Intolerance;	Ciclosporin			S	Unknown			Not Reported	
Dyspnoea; Elbow	Enbrel			S	Unknown			Not Reported	
Deformity; Fatigue; Jaw	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Fracture; Joint Swelling;	Methotrexate			S	Unknown			Not Reported	
Musculoskeletal Pain;	Mycophenolate Mofetil			S	Unknown			Not Reported	
Neck Pain; Overlap	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Syndrome; Pain In									
Extremity; Pain In Jaw;									
Red Blood Cell									
Sedimentation Rate	Xeljanz			C	Unknown			Not Reported	
Abnormal; Sle Arthritis;									
Toxicity To Various									
Agents; Weight Decreased									

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08-Apr-2020	17647436	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356481-00			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Polyarthritits; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17648751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356478-00			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deformity; Movement Disorder; Polyarthritits; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17649052	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029653			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Rheumatoid Arthritis	Orencia	S	Unknown		Bristol Myers Squibb
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Milligram, Q2wk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram, Q6wk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	C	Unknown		Not Reported
	Wellbutrin	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17649456	DIRECT	Y	DE			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Test Positive	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Oseltamivir Phosphate			C				Not Reported
	Pantoprazole Sodium			C				Not Reported
	Sodium Chloride 0.9% 1000 MI			C				Not Reported
	Azithromycin 500 Mg			C				Not Reported
	Zosyn 3.375 G			C				Not Reported
	Sodium Bicarbonate			C				Not Reported
	Atropine			C				Not Reported
	Epinephrine			C				Not Reported
	Acetaminophen			C				Not Reported
	Ceftriaxone			C				Not Reported

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08-Apr-2020	17649584	NON-EXPEDITED			US-TEVA-2020-US-1213903			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response Unexpected	Hydroxychloroquine Sulfate			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17649858	NON-EXPEDITED			NVSC2020US093707			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Hydroxychloroquine Sulfate			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17651020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029403		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lyrica			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	

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Sulfasalazine

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17651063	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-028965			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
Piroxicam			C	Unknown			Not Reported	
Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17651130	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029423		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Condition Aggravated; Deformity; Drug	Orencia	S	Unknown		Bristol Myers Squibb
Ineffective; Dyspnoea;	Acetaminophen	S	Unknown		Not Reported
Gait Disturbance; Hand	Actemra	S	Unknown		Not Reported
Deformity; Injection Site	Apo-Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Reaction; Off Label Use;	Apo-Ramipril	S	Unknown	Unk, Qd	Not Reported
Product Use Issue;	Folic Acid	S	Unknown		Not Reported
Rheumatoid Arthritis;	Humira	S	Subcutaneous		Not Reported
Sciatica	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Levothyroxine	S	Unknown	Unk, Qd	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
	Acetaminophen, Caffeine, Dihydrocodeine Bitartrate	C	Unknown		Not Reported
	Acetaminophen;Codeine	C	Unknown		Not Reported
	Dorzolamide	C	Ophthalmic	Unk, Bid	Not Reported
	Hydrochloride/Timolol Maleate				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17651159	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029452			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Orencia			S	Unknown			Bristol Myers Squibb
Drug Hypersensitivity;	Sulfasalazine			S	Unknown			Not Reported
Drug Intolerance; Psoriatic	Simponi			S	Unknown			Not Reported
Arthropathy; Rash; Red	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Blood Cell Sedimentation								
Rate Increased; Sciatica;	Remicade			S	Unknown			Not Reported
Sinusitis; Therapeutic								
Product Effect Incomplete;								
Treatment Failure								

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

	Mycophenolate Mofetil	S	Unknown						Not Reported
	Methotrexate	S	Unknown						Not Reported
	Lyrica	S	Unknown						Not Reported
	Hydroxychloroquine Sulfate	S	Unknown						Not Reported
	Humira	S	Unknown		40 Milligram				Not Reported
	Enbrel	S	Unknown						Not Reported
	Arava	S	Unknown						Not Reported
	Actemra	S	Unknown						Not Reported
	Hydroxychloroquine	S	Unknown						Not Reported
	Piroxicam	C	Unknown						Not Reported
	Prednisone	C	Unknown						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17651582	DIRECT	Y	OT			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Hydroxychloroquine			S	Oral				Not Reported
Electrocardiogram Qt	Amiodarone			S	Oral				Not Reported
Prolonged	Azithromycin			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	11257960	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-046061		45 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein	Orencia			S	Intravenous (not	Unk			Bristol Myers Squibb
Abnormal; Drug					otherwise specified)				
Ineffective; Drug	Enbrel			S	Subcutaneous	Unk			Not Reported
Intolerance; Interstitial	Hydroxychloroquine Phosphate			S	Unknown				Not Reported
Lung Disease; Joint	Actemra			S	Unknown	Unk			Not Reported
Swelling; Off Label Use;	Kineret			S	Unknown	Unk			Not Reported
Pain; Product Use Issue;									
Red Blood Cell									

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

Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	1 MI, Qwk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	7 Mg, Qd	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Mycophenolic Acid	S	Unknown		Not Reported
	Methotrexate	S	Unknown	1 Milliliter	Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	13064952	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161217720			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	14501669	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-007157		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C- Reactive Protein	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
Abnormal; C-Reactive Protein Increased;	Apo-Folic Acid			S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
Condition Aggravated;	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
Disability; Drug	Sulfasalazine			S	Oral	500 Milligram, Bid		Not Reported
Hypersensitivity; Drug	Sulfasalazine			S	Oral	1000 Milligram		Not Reported
Ineffective; Drug-Induced	Arava			S	Oral	20 Milligram, Qd		Not Reported
Liver Injury; Fall; Fatigue;	Co Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
Femur Fracture;	Co Atenolol			S	Unknown	20 Milligram, Qd		Not Reported
Haematocrit Decreased;								
Haemoglobin Decreased;								
Impaired Healing; Joint								

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

Swelling; Multiple	Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
Fractures; Musculoskeletal	Enbrel	S	Subcutaneous	Unk	Not Reported
Pain; Off Label Use;	Humira	S	Subcutaneous	Unk	Not Reported
Osteoporosis; Pain; Pain	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
In Extremity; Peripheral	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
Swelling; Rash; Red Blood	Methotrexate Sodium	S	Oral	20 Milligram, Q2wk	Not Reported
Cell Count Decreased;	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
Red Blood Cell	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
Sedimentation Rate	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
Abnormal; Rheumatoid	Methotrexate Sodium	S	Oral	20 Milligram, Qwk	Not Reported
Arthritis; Synovitis	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
	Naprosyne	S	Oral	1000 Milligram, Qd	Not Reported
	Naprosyne	S	Oral	100 Milligram, Qd	Not Reported
	Naprosyne	S	Oral	500 Milligram, Bid	Not Reported
	Palafer Cf	S	Unknown	1 Dosage Form, 1 Every 24 Hrs	Not Reported
	Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown	40 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Ascorbic Acid	S	Unknown	Unk Unk, Qd	Not Reported
	Actemra	S	Unknown		Not Reported

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

Naproxen Sodium	S	Oral	500 Milligram, Bid	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, Qd	Not Reported
Naproxen Sodium	S	Unknown	1000 Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Cyclical	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	1000 Milligram, Qd	Not Reported
Celecoxib	S	Unknown		Not Reported
Folic Acid	S	Unknown	5 Milligram, Q2wk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	400 Milligram	Not Reported
Folic Acid	S	Unknown	5 Unk	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qwk	Not Reported
Hydroxychloroquine	S	Unknown	40 Unk	Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	S	Unknown		Not Reported
Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Methotrexate	S	Unknown	25 Milligram, Qwk	Not Reported

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

Naprosyn [Naproxen Sodium]	S	Oral	1000 Milligram, Qd	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn [Naproxen Sodium]	S	Oral	100 Milligram, Qd	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Teva Pantoprazole	S	Unknown	40 Milligram, Qd	Not Reported
Vitamin C [Ascorbic Acid]	S	Unknown	Unk, Qd	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, Qd	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celecoxib	C	Oral	200 Milligram, Qd	Not Reported
Prednisone	C	Intracardiac	5 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	14750177	EXPEDITED (15-DAY)		DE, OT	IT-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-031026		67 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Aspirin			S	Unknown	Unk		Bristol Myers Squibb
	Influenza Vaccine			S	Unknown	Unk		Not Reported
	Celecoxib			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Asa			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	15219753	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-NODEN PHARMA DAC-NOD-2018-000052			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Rasilez	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Noden Pharma
	Rasilez	S			Noden Pharma
	Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
	Prednisolone	S	Transplacental	Unk	Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk, If Required; Trimester: First+Second;From Gestational Week 0-14	Not Reported
	Salbutamol Sulfate	S	Transplacental	Unk	Not Reported
	Delix /00885601/	S	Transplacental	Maternal Dose 20 Mg, Qd (Exposure Duration 0-13+6 Weeks)	Not Reported
	Delix /00885601/ Quensyl	S			Not Reported
	Quensyl	S	Transplacental	400 [Mg/D (2x200)]; 0-13.6 Gestational Week;From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Unk	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
	Acetylsalicylic Acid Pantozol /01263204/	S			Not Reported
	Pantozol /01263204/	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week;From Gestational Week 0-14 (Busco Pantoprazole)	Not Reported
	Toraseamide	S	Transplacental	Unk	Not Reported
	Toraseamide	S	Transplacental	From Gestational Week 0-14	Not Reported
	Toraseamide	S	Transplacental	Unk	Not Reported
	Advagraf	S	Transplacental	6 [Mg/D]; 0-13.6 Gestational Week, From Gestational Week 0-14	Not Reported

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

Advagraf	S	Transplacental	Unk	Not Reported
Advagraf	S			Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Ezetimibe Msd	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Exposure Duration: 0-14 Weeks. Trimester: First; Probably Only In Hospital In Week 5.	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Novaminsulfon	S	Transplacental	300 Milligram, Qd	Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Clexane	S			Not Reported
Heparin Lmw	S	Transplacental	Unknown	Not Reported
Heparin Lmw	S			Not Reported
Enoxaparin	S	Transplacental	From Gestational Week 0-14	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Rituximab	S	Transplacental	Unk	Not Reported
Heparin	S	Transplacental	Unk (Low Molecular Weight Heparin)	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

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

	Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported				
	Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported				
	Cyclophosphamide	C			Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	15551940	EXPEDITED (15-DAY)	CA		DE-TEVA-2018-DE-967934			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental			Actavis	
	Torem			S	Transplacental	100 [Mg/D]		Not Reported	
	Quensyl			S	Transplacental	200 Milligram Daily; Daily Dose: 400 Mg Milligram(S) Every Days		Not Reported	
	Rituximab			S	Transplacental	Last Time In December 2011: Pre Or Periconceptional		Not Reported	
	Inegy			S	Transplacental	40 [Mg/D] / 10 [Mg/D]		Not Reported	
	Delix (Ramipril)			S	Transplacental	20 [Mg/D]		Not Reported	
	Advagraf			S	Transplacental	6 [Mg/D]		Not Reported	
	Pantozol			C	Transplacental	40 [Mg/D]		Not Reported	
	Albuterol			C	Transplacental	Unk, Prn		Not Reported	
	Cytotec			C	Transplacental	Unk		Not Reported	
	Cyclophosphamid			C	Transplacental	3000 [Mg Cumulative]/ April -August 2011		Not Reported	
	Xarelto 10 Mg Filmtabletten			C	Transplacental	Not Known, If Treatment Started Before Or After Missed Abortion.		Not Reported	
	Clexane			C	Transplacental	200 [Mg/D (2x100)]		Not Reported	
	Novaminsulfon			C	Unknown	For 5 Weeks		Not Reported	
	Aliskiren			C	Transplacental	300 [Mg/D]		Not Reported	

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

Mifegyne	C	Transplacental	Unk	Not Reported
Rasilez	C	Transplacental	300 [Mg/D]	Not Reported
Salbutamol	C	Transplacental	If Required	Not Reported
Prednisolon	C	Transplacental	Daily Dose: 10 Mg Milligram(S) Every 2 Day	Not Reported
Ass	C	Transplacental	100 [Mg/D]	Not Reported
Novaminsulfon	C	Transplacental	Probably Only In Hospital In Week 5	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	15623961	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2557378-00		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Blood Iron	Humira			S	Subcutaneous			Not Reported
Abnormal; Condition	Actemra			S	Subcutaneous			Not Reported
Aggravated;	Actemra			S				Not Reported
Contraindicated Product	Arava			S	Oral			Not Reported
Administered; Disease	Cellcept			S	Unknown			Not Reported
Progression; Drug	Enbrel			S	Unknown			Not Reported
Hypersensitivity; Drug	Hydroxychloroquine			S	Unknown			Not Reported
Ineffective; Drug	Lyrica			S	Oral			Not Reported
Intolerance; Joint Swelling;	Lyrica			S	Oral			Not Reported
Multiple Allergies; Multiple	Methotrexate			S	Unknown			Not Reported
Allergies; Musculoskeletal	Orencia			S	Unknown			Not Reported
Pain; Musculoskeletal	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
Pain; Off Label Use;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Psoriatic Arthropathy;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Rash; Red Blood Cell	Rituxan			S	Intravenous (not			Not Reported
Sedimentation Rate								
Increased; Rheumatoid								
Arthritis; Sciatica;								
Sinusitis; Swelling;								
Therapeutic Product Effect								
Incomplete; Treatment								
Failure; Unevaluable								
Event								

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			otherwise specified)	
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo Mycophenolate	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Sodium Aurothiomalate	S	Oral		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Cyclosporine	S	Oral		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Cimzia	S	Subcutaneous		Not Reported
Certolizumab Pegol	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Piroxicam	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Pregabalin	S	Oral		Not Reported
Teva Mycophenolate	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Piroxicam	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	15635156	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		52 YR	Female	CAN

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BMS-2018-105525

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Gram, Q2wk		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	2000 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	Unk Unk, Q2wk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	15957810	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20190213510			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Decreased; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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Orencia	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17533403	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243621		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Crohn'S Disease; Drug Hypersensitivity; Drug Ineffective; Lower Respiratory Tract Infection; Nasopharyngitis; Off Label Use; Product Use In Unapproved Indication	Stelara			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Simponi			S	Subcutaneous			Janssen	
	Gabapentin			S	Unknown			Not Reported	
	Perindopril			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Otezla			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17558247	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316516		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Simponi	S	Subcutaneous	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported
	Methotrexate Sodium	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17577764	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200329945			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not			Not Reported	

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		otherwise specified)	
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Acetaminophen	C	Oral	Not Reported
Diphenhydramine	C	Oral	Not Reported
Hydroxychloroquine	C		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	1757767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329960			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Sarilumab			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17605627	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332798			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17605642	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332799		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported

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Zoster; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	1.0 Dosage Forms	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Lyrica	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17605650	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200332795		38 YR	Female	CAN

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

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17605716	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332774			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Subcutaneous			Not Reported	
	Anakinra			S	Oral			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17611318	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160614521			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthritis; Asthenia; Bone	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	

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Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Remicade	S	Intravenous (not otherwise specified)	Ndc: 412545	Not Reported
	Arava	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17623404	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342106		48 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Prednisolone			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17623464	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340472		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use	Simponi			S	Subcutaneous			Janssen	
	Celebrex			S	Unknown			Not Reported	
	Celebrex			S				Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Naprosyn /00256201/			S	Unknown			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17647143	EXPEDITED (15-DAY)		HO, LT, OT	MX-ALKEM LABORATORIES LIMITED-MX-ALKEM- 2020-01066		29 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess; Myositis; Nocardiosis; Perinephric Abscess; Pneumonia; Pyomyositis	Mycophenolate Mofetil			S	Oral	2.5 Gram, Qd		Alkem	
	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported	
	Prednisone			S	Oral	30 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17648078	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029659		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Anaphylactic Reaction;	Orencia	S	Unknown	Unk	Bristol Myers Squibb
Arthralgia; Cardiovascular	Cimzia	S	Subcutaneous	Unk	Not Reported
Disorder; Drug	Enbrel	S	Unknown	Unk	Not Reported
Hypersensitivity; Drug	Gold	S	Unknown	Unk Unk, Qd	Not Reported
Ineffective; Inflammation;	Humira	S	Subcutaneous	Unk	Not Reported
Joint Swelling; Red Blood	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Cell Sedimentation Rate	Leflunomide	S	Unknown	Unk	Not Reported
Increased; Urticaria	Methotrexate	S	Oral	22.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Parenteral	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported
	Azathioprine	C	Unknown	Unk, Qd	Not Reported
	Ciclosporin	C	Unknown	Unk	Not Reported
	Minocycline	C	Unknown	Unk	Not Reported
	Penicillamine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17648606	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029670		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
Ineffective; Ill-Defined	Actemra			S	Subcutaneous			Not Reported	
Disorder; Infection; Loss Of Consciousness;	Anakinra			S	Subcutaneous	100 Milligram		Not Reported	
Mobility Decreased;									

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

Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qh	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	175 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate Sodium	S	Unknown	35 Milligram, Qwk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Milligram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Risedronate	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17648737	EXPEDITED (15-DAY)		OT	DE-GLAXOSMITHKLINE-DE2020061233		42 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis; Erythema	Ceftriaxone Sodium			S	Unknown	Unk		Glaxosmithkline	
Nodosum; Herpes	Streptomycin			S	Unknown	Unk		Glaxosmithkline	
Dermatitis; Herpes	Cotrimoxazole			S	Unknown	Unk		Glaxosmithkline	
Simplex; Immune Reconstitution	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline	
Inflammatory Syndrome; Immune Reconstitution	Sulfamethoxazole + Trimethoprim			S	Unknown	960 Mg, Qd		Glaxosmithkline	
Inflammatory Syndrome; Lymphoedema; Mass;	Ceftriaxone			S	Unknown	Unk		Glaxosmithkline	
Nodule; Panniculitis; Papilloma Viral Infection;	Azathioprine			S	Unknown	Unk		Glaxosmithkline	

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

Periorbital Oedema; Periorbital Swelling	Acyclovir	S	Unknown	Every 4 Hours.	Glaxosmithkline
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Dose Increased	Not Reported
	Prednisone	S	Unknown	Dose Reduced	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17648841	EXPEDITED (15-DAY)		HO	US-ADVANZ PHARMA-202003002755			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia	
	Hydroxychloroquine			S				Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17649603	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1219671		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbycusis;	Gabapentin			S	Oral			Actavis	
	Fentanyl			S	Unknown			Cephalon	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

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

Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Oxycontin	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	2.5 Gram Daily;	Not Reported
	Acetaminophen	C			Not Reported
	Aclasta	C			Not Reported
	Docosahexaenoic Acid/Eicosapentaenoic Acid	C			Not Reported
	Nasonex	C			Not Reported
	Prednisone	C			Not Reported
	Trazodone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17651306	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029788			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652023	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146043			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthritis; Drug Ineffective; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate Sodium			S	Oral			Pfizer	
	Methotrexate Sodium			S	Subcutaneous			Pfizer	
	Sulfasalazine			S	Unknown			Pfizer	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652025	EXPEDITED (15-DAY)		OT	RO-ADVANZ PHARMA-202003002774			Unknown	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002411			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Eosinophilic Myocarditis; Exposure During Pregnancy; Rash	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652041	EXPEDITED (15-DAY)		OT	CA-ADVANZ PHARMA-201909000624			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy; Depression; Drug Ineffective; Drug Intolerance; Hypersensitivity; Myelopathy; Neuropathy	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Arava			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Pyridoxine Hydrochloride			S	Unknown	Unk		Not Reported	

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Peripheral	Lasix	C	Unk	Not Reported
	Xarelto	C	Unk	Not Reported
	Vitamin B12 Nos	C	Unk	Not Reported
	Calcium	C	Unk	Not Reported
	Bisoprolol	C	Unk	Not Reported
	Fish Oil	C	Unk	Not Reported
	Magnesium	C	Unk	Not Reported
	Ramipril	C	Unk	Not Reported
	Buprenorphine	C	Unk	Not Reported
	Vitamin D	C	Unk	Not Reported
	Xeljanz	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Vitamin B6	C	Unk	Not Reported
	Arava	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652062	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1220063		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural Thickening; Presbycusis;	Gabapentin			S	Unknown	200 Milligram Daily;		Actavis
	Fentanyl			S	Unknown			Cephalon
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Intramuscular			Not Reported

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

Renal Impairment; Skin Lesion; Treatment Failure	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown 2.5 Gram Daily;	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Ascorbic Acid	C	Unknown	Not Reported
	Biotin	C		Not Reported
	D-Alpha Tocopherol	C	Unknown 2400 Milligram Daily;	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown 2.5 Milligram Daily;	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown 400 Iu (International Unit) Daily;	Not Reported
	Esomeprazole	C	Unknown 80 Milligram Daily;	Not Reported
	Ferrous Fumarate	C	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Hydroxocobalamin	C		Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Nasonex	C	Unknown 4 Dosage Forms Daily;	Not Reported
	Nicotinamide	C		Not Reported
	Nortriptyline Hydrochloride	C	Oral 40 Milligram Daily;	Not Reported
	Nortriptyline Hydrochloride	C	Oral	Not Reported
	Prednisone	C	Unknown 5 Gbq Daily;	Not Reported
	Pyridoxine Hydrochloride	C		Not Reported
	Riboflavin	C		Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Sodium Ascorbate	C		Not Reported
	Thiamine Hydrochloride	C		Not Reported
	Thiamine Mononitrate	C		Not Reported
	Trazodone Hydrochloride	C	Oral 50 Milligram Daily;	Not Reported
	Tylenol	C	Unknown 1000 Milligram Daily;	Not Reported
	Vitamin A	C		Not Reported

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Vitamin C [Ascorbic Acid]	C			Not Reported
Vitamin D3	C			Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652287	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1036031		75 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematochezia	Furosemide			S		Unk		Not Reported
	Dabigatran Etxilate			S	Oral	300 Milligram, Qd		Mylan
	Daparox /00830803/			S		Unk		Mylan
	Lamictal			S		Unk		Mylan
	Plaquenil /00072602/			S		Unk		Mylan
	Valium			S		Unk		Mylan
	Sotalol			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17654933	DIRECT	Y	DE			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Endotracheal Intubation Complication	Hydroxychloroquine			S	Oral			Teva
	Hydroxychloroquine			S	Oral			Teva
	Azithromycin			C				Not Reported
	Albuterol			C				Not Reported
	Lasix			C				Not Reported
	Zosyn			C				Not Reported
	Humulin R			C				Not Reported
	Vancomycin			C				Not Reported
	Lovenox			C				Not Reported
	Tamiflu			C				Not Reported
	Rocephin			C				Not Reported
	Acetaminophen			C				Not Reported
	Zofran			C				Not Reported
	Ns			C				Not Reported

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D50w	C	Not Reported
Pravachol	C	Not Reported
Ativan	C	Not Reported
Doxycycline	C	Not Reported
Propofol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	15635730	EXPEDITED (15-DAY)		OT	CA-ABBVIE-15K-028-1478917-00		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	3 Years		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	16946977	EXPEDITED (15-DAY)		LT, OT	CA-GLAXOSMITHKLINE-CA2019AMR190534		40 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Fatigue; Off Label Use; Suicidal Ideation	Benlysta			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Glaxosmithkline	
	Benlysta			S		Unk		Glaxosmithkline	
	Benlysta			S		Unk		Glaxosmithkline	
	Benlysta			S		Unk		Glaxosmithkline	
	Benlysta			S		200 Mg		Glaxosmithkline	
	Benlysta			S	Subcutaneous	Unk		Glaxosmithkline	
	Imuran			S	Oral	200 Mg, Qd		Glaxosmithkline	
	Plaquenil			S		400 Mg, Qd		Not Reported	
	Prednisone			S		20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17395563	NON-EXPEDITED			US-AMGEN- USASP2020020542		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17653559	NON-EXPEDITED		OT	US-SA-2020SA089843			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Arava			S				Sanofi	
	Plaquenil			S				Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17653880	EXPEDITED (15-DAY)		DE	FR-TEVA-2020-FR- 1221561		70 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Ebilfumin 75 Mg, Gélule			S	Oral	75 Mg		Teva
	Ceftriaxone Mylan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Plaquenil			S	Oral	At D1 Then 400mg / Day, Unit Dose: 800 Mg		Not Reported
	Coversyl 5 Mg, Comprimé Pelliculé Sécable			C	Oral	5 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654641	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030070		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654647	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-029994			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance;	Orencia			S	Unknown			Bristol Myers Squibb

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

Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
	Diclofenac	C	Oral	100 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654650	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030021		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb
	Cimzia			S	Subcutaneous	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	5 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram, 2 Every 1 Day		Not Reported

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

Prednisone			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654666	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1221569			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycine Dihydratee			S	Oral	500 Mg		Not Reported	
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654748	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3357368-00		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hepatocellular Injury	Kaletra 200/50			S	Oral	2 Comp/12h		Not Reported	
	Kaletra 200/50			S				Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported	
	Ceftriaxona			S				Not Reported	
	Hidroxiclороquina			S	Oral	200mg/12h		Not Reported	
	Hidroxiclороquina			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654834	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146015			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuropathy Peripheral	Methotrexate Sodium			S	Unknown			Pfizer	
	Celebrex			S	Unknown			Pfizer	
	Sulfasalazine			S	Unknown			Pfizer	
	Xeljanz			S	Unknown			Pfizer	
	Codeine Phosphate			S	Unknown			Not Reported	

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

Leflunomide	S	Unknown	Not Reported
Plaquenil S	S	Unknown	Not Reported
Azathioprine Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17655309	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202003002613			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Fatigue; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Triatec			C				Not Reported
	Doliprane			C				Not Reported
	Levothyrox			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17655685	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1219067		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Alendronate Sodium			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Ibuprofen			S	Oral			Actavis
	Ibuprofen			S	Oral	600 Milligram Daily;		Actavis
	Ibuprofen			S	Oral			Actavis
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr

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

Daily Activities; Nausea;	Methotrexate	S	Unknown	Barr
Panniculitis; Peripheral	Apo-Ibuprofen	S	Oral	Not Reported
Swelling; Psoriatic	Apo-Leflunomide	S	Oral	Not Reported
Arthropathy; Rash; Rash	Apremilast	S	Unknown	Not Reported
Pruritic; Red Blood Cell	Apremilast	S	Unknown	Not Reported
Sedimentation Rate;	Apremilast	S	Unknown	Not Reported
Rheumatoid Arthritis;	Apremilast	S	Unknown	Not Reported
Rheumatoid Nodule; Skin	Apremilast	S	Unknown	Not Reported
Necrosis; Skin Ulcer;	Cimzia Single-Use Prefilled	S	Subcutaneous	Not Reported
Synovitis; Tendonitis;	Syringe	S	Subcutaneous	Not Reported
Tenosynovitis; Tongue	Enbrel	S	Subcutaneous	Not Reported
Disorder; Ulcer	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Infliximab	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Benadryl	C		Not Reported
	Colchicine	C	Oral	Not Reported
	Dexilant	C		Not Reported
	Febuxostat	C		Not Reported
	Folic Acid	C		Not Reported

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

Gravol	C			Not Reported
Mogadon	C	Oral		Not Reported
Nitrazepam	C	Unknown		Not Reported
Oxycodone	C			Not Reported
Prednisone	C			Not Reported
Uloric	C	Unknown	160 Milligram Daily;	Not Reported
Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17655811	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220302		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Fluctuation; Blood Pressure Increased;	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
Colitis; Dental Caries;	Amlodipine Besilate			S	Oral			Teva
Diabetes Mellitus	Gliclazide			S	Unknown			Not Reported
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Leflunomide			S	Unknown			Barr
Gastrointestinal Disorder; Haematochezia;	Methotrexate			S	Subcutaneous			Barr
Hypertension;	Asacol			S	Unknown	2400 Milligram Daily;		Not Reported
Musculoskeletal Stiffness; Pain In Extremity;	Diamicron			S	Unknown			Not Reported
Peripheral Swelling; Rheumatoid Arthritis;	Enbrel			S	Subcutaneous			Not Reported
Vitamin D Deficiency; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported

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

Methylprednisolone Acetate	C	Intravenous (not otherwise specified)	Not Reported
Methylprednisolone Acetate	C	Intra-articular	Not Reported
Rosuvastatin Calcium	C		Not Reported
Tylenol	C		Not Reported
Vitamin D3	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17655893	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA-202003002355			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence	Hydroxychloroquine			S	Unknown	(Strength: 400mg 2x15 Cprev		Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656013	EXPEDITED (15-DAY)		OT	GR-PBT-000004		68 YR	Unknown	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatomyositis; Disease Progression; Drug Ineffective; Product Use In Unapproved Indication; Vasculitic Rash	Tacrolimus			S	Unknown			Panacea Biotec	
	Tacrolimus			S	Unknown			Panacea Biotec	
	Thiamazole			C	Unknown			Not Reported	
	Prednisolone			S	Unknown			Not Reported	
	Prednisolone			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported	
	Hydroxychloroquine			S	Intraocular	200mg Oculus Dexter (Od)		Not Reported	
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported	
	Hydroxychloroquine			S	Unknown	Dose Was Doubled		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Intravenous Pulse (1 Gr).		Not Reported	
	Methylprednisolone			S	Intravenous (not	Intravenous Pulse		Not Reported	

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Methylprednisolone	S	otherwise specified)	Intravenous Pulse	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	Two Monthly Intravenous Pulses	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown	Two Weeks Apart	Not Reported
Rituximab	S	Unknown	Two Weeks Apart	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656614	DIRECT	Y	OT			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656633	DIRECT		OT			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Dyspnoea	Hydroxychloroquine	Y		S	Oral	Quantity:10 Tablet(S);		Not Reported
	Breo			C				Not Reported
	Dupixent			C				Not Reported
	Green Tea			C				Not Reported
	Magnesium			C				Not Reported
	Black Seed Oil			C				Not Reported
	Blessed Thistle			C				Not Reported
	Sunflower Lecithin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17657153	EXPEDITED (15-DAY)		OT	PL-AMNEAL PHARMACEUTICALS- 2020-AMRX-01107		54 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Breast Cancer	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2x/Day	Amneal

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17657180	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220398		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Fluctuation; Blood Pressure Increased;	Amlodipine Besilate			S	Oral	5 Milligram Daily;		Teva
Colitis; Dental Caries;	Gliclazide			S	Unknown			Not Reported
Diabetes Mellitus	Leflunomide			S	Unknown			Barr
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Methotrexate			S	Subcutaneous			Barr
Gastrointestinal Disorder; Haematochezia;	Enbrel			S	Subcutaneous			Not Reported
Hypertension;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Musculoskeletal Stiffness; Pain In Extremity;	Plaquenil			S	Unknown			Not Reported
Peripheral Swelling; Rheumatoid Arthritis;	Orencia			S	Unknown			Not Reported
Vitamin D Deficiency; Weight Increased	Humira			S	Subcutaneous			Not Reported
	Asacol Also Known As Mesalamine			S	Unknown	2400 Milligram Daily;		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Atacand Plus			C	Unknown			Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Ebastine			C	Unknown			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported

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

Folic Acid	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17657558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1220718			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Ramipril			S	Oral			Actavis
	Ramipril			S	Unknown			Actavis
	Acetaminophen			S	Unknown			Not Reported
	Dorzolamide/Timolol			S	Unknown	2 Dosage Forms Daily;		Actavis
	Dorzolamide/Timolol			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	15401123	EXPEDITED (15-DAY)		OT	DE-ABBVIE-18K-062-2483634-00		63 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported

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

Hydroxychloroquine	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Plaquenil	S	Oral		Not Reported
Plaquenil	S	Oral		Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Apo-Leflunomide	S	Oral	Tablet	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous Rituxan	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Methotrexat	S	Subcutaneous	20mg	Not Reported
Methotrexat	S	Oral	20mg, Solution For Injection/Infusion	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20mg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw Txt	Not Reported
Remicade	S	Intravenous (not	3 Mg Powder For Solution	Not Reported

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

	Remicade	S	otherwise specified)	Intravenous					
			Intravenous (not otherwise specified)	3 Mg Powder For Solution					Not Reported
	Leflunomide	S	Unknown	Film Coated Tablet					Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk					Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk					Not Reported
	Simponi	S	Subcutaneous						Not Reported
	Xeljanz	C	Unknown	2 Ot, Qd					Not Reported
	Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)					Not Reported
	Xeljanz	C	Oral	2 Ot, Qd					Not Reported
	Xeljanz	C	Unknown	2 Ot, Qd					Not Reported
	Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)					Not Reported
	Xeljanz	C	Oral	2 Ot, Qd					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	15621780	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-18K-028-2557337-00		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Humira			S	Subcutaneous				Not Reported
Adverse Event;	Apo-Leflunomide			S	Oral				Not Reported
Arthrodesis; Arthropathy;	Cefazolin			S	Intramuscular				Not Reported
Drug Hypersensitivity;	Cimzia			S	Subcutaneous				Not Reported
Drug Ineffective;	Enbrel			S	Unknown				Not Reported
Hospitalisation; Infection;	Methotrexate			S	Subcutaneous				Not Reported
Limb Discomfort; Limb	Orencia			S	Unknown				Not Reported
Operation; Rash;	Plaquenil			S	Unknown				Not Reported
Rheumatoid Arthritis;	Remicade			S	Intravenous (not otherwise specified)				Not Reported
Shoulder Arthroplasty	Rituxan			S	Intravenous (not				Not Reported

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

Rituximab	S	otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)	Not Reported
Leflunomide	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Viread	C	Oral	Not Reported
Naproxen	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	16079912	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-06123		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Infliximab			S	Unknown	Unknown		Not Reported
Arthralgia; Cardiovascular	Adalimumab			S	Unknown	Unknown		Not Reported
Disorder; Contraindicated	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
Product Administered;	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe		Not Reported
Drug Hypersensitivity;	Enbrel			S	Unknown	Unknown		Not Reported
Drug Ineffective;	Gold			S	Unknown	Unknown		Not Reported
Inflammation; Joint	Gold			S	Unknown	Unknown		Not Reported
Swelling; Muscle Spasms;	Humira			S	Subcutaneous	Unknown, Solution		Not Reported
Off Label Use; Red Blood	Humira			S	Unknown	Unknown		Not Reported
Cell Sedimentation Rate	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
Increased; Urticaria	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported

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

Plaquenil	S	Oral	Unknown	Not Reported
Plaquenil	S	Oral	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Subcutaneous	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown, Solution	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Abatacept	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Subcutaneous	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Actemra	C	Unknown	Unknown	Not Reported
Azathioprine	C	Unknown	Unknown	Not Reported
Ciclosporin	C	Unknown	Unknown	Not Reported
Minocycline	C	Unknown	Unknown	Not Reported
Penicillamine	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported
Tocilizumab	C	Unknown	Unknown	Not Reported
D-Penicillamine	C	Unknown	Unknown	Not Reported
Prednisolone	C	Unknown		Not Reported
Cyclosporin	C	Unknown	Unknown	Not Reported
Phenylbutazone	C	Unknown	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	17658279	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01638		31 YR	Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Febrile Neutrophilic Dermatitis	Hydroxychloroquine			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	17658282	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-01639		42 YR	Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Febrile Neutrophilic Dermatitis	Hydroxychloroquine			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	17658365	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028- 2762682-00		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Pressure Increased; Drug Ineffective; Drug Ineffective; Gout; Loss Of Personal Independence In Daily Activities; Metabolic Disorder; Metabolic Surgery; Middle Insomnia; Musculoskeletal Stiffness; Off Label Use; Pain In Extremity; Product Use Issue; Synovitis; Weight Increased	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Folic Acid			C				Not Reported	
	Allopurinol			C				Not Reported	
	Pantoloc			C	Unknown			Not Reported	
	Zyloprim			C				Not Reported	

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

Clomipramine	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	17658388	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020014951			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Apo-Leflunomide			S		20 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		200 Milligram		Not Reported
	Methotrexate			S		20 Milligram		Not Reported
	Orencia			S		Unk		Not Reported
	Sulfasalazine			S		1 Gram		Not Reported
	Xeljanz			C	Oral	5 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	17658450	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030120			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Orencia			S	Unknown			Bristol Myers Squibb
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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Rituximab	S	otherwise specified)		Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
Varicella Zoster Vaccine Live	S	Unknown		Not Reported
Desoximetasone	S	Subcutaneous		Not Reported
Diclofenac	C	Oral		Not Reported
Xeljanz	C	Unknown	100 Milligram	Not Reported
	C	Oral	5 Milliliter, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	12776517	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-076645		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

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

Rituximab		S		otherwise specified) Intravenous drip		Unk	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	14778692	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009922			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Drug Ineffective; Hepatitis; Therapeutic Response Decreased	Hydroxychloroquine			S	Oral	Unk		Apotex	
	Leflunomide			S	Oral	Unk		Apotex	
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
	Methotrexate			C	Unknown	20 Mg, Q.Wk.		Not Reported	
	Sulfasalazine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15624165	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2556702-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown	Solution		Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Orencia			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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

Remicade	S				Not Reported
Rituxan	S	Intravenous (not otherwise specified)			Not Reported
Enbrel	S	Unknown			Not Reported
Hydroxychloroquine Sulfate	S	Unknown			Not Reported
Actemra	S	Unknown			Not Reported
Apo-Leflunomide	S	Oral			Not Reported
Plaquenil	S	Unknown			Not Reported
Simponi	C	Subcutaneous			Not Reported
Xeljanz	C	Unknown			Not Reported
Wellbutrin	C	Unknown	Extended Release		Not Reported
Sulfasalazine	C	Unknown			Not Reported
Bupropion	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15686123	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573639-00		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia;	Humira			S	Subcutaneous			Not Reported
Arthritis; Blood Cholesterol	Humira			S				Not Reported
Increased; C-Reactive Protein Abnormal; C-Reactive Protein	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Increased; Condition	Actemra			S				Not Reported
Aggravated;	Apo Hydroxyquine			S	Unknown			Not Reported
Contraindicated Product	Arava			S	Unknown			Not Reported
Administered; Drug	Arava			S				Not Reported
Hypersensitivity; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Fibromyalgia;	Methotrexate			S	Unknown			Not Reported
Herpes Zoster; Infection;	Methotrexate			S	Unknown			Not Reported
Joint Swelling;	Methotrexate			S	Unknown	Solution		Not Reported
Leukopenia; Liver	Methotrexate			S	Unknown			Not Reported
Function Test Abnormal;	Methotrexate			S	Unknown			Not Reported
Off Label Use; Oral Pain;								
Peripheral Swelling;								

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Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified) Powder For Solution	Not Reported
	Sodium Aurothiomalate	S	Intramuscular Injection Bp	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C	Unknown	Not Reported
	Ativan	C		Not Reported
	Codeine	C	Unknown	Not Reported
	Darifenacin	C		Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Intramuscular	Not Reported
	Dilaudid	C	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Furosemide	C		Not Reported

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Hydromorphone	C	Unknown		Not Reported
Kadian	C		Sustained-Release	Not Reported
Kenalog	C	Intra-articular		Not Reported
Kenalog	C			Not Reported
Loperamide	C	Unknown		Not Reported
Norflex	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray,Metered Dose	Not Reported
Oxyneo	C	Unknown	Extended Release	Not Reported
Pantoprazole Sodium	C			Not Reported
Restasis	C	Unknown		Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported
Trimethoprim	C	Unknown		Not Reported
Urispas	C			Not Reported
Vagifem	C	Vaginal		Not Reported
Dexamethason	C	Intramuscular		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex	C		(Extended Release)	Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Lasix	C			Not Reported
Morphine Sulphate	C	Unknown		Not Reported
Dyclone	C			Not Reported
Benadryl	C	Unknown		Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Darifenacin Hydrobromide	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoloc	C			Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Dexamethasone	C	Unknown		Not Reported
Orphenadrine Citrate	C			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15708189	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2586143-00		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Zostavax			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Varicella Zoster Vaccine			S	Unknown	Liquid Intramuscular		Not Reported	
	Etanercept			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15713147	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2588025-00		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Female; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Humira			S	Subcutaneous			Not Reported	
	Arava			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquin			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

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

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15848951	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2633323-00		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; Gastric Disorder; General Physical Health Deterioration; Insomnia; Nausea; Rheumatoid Arthritis; Sleep Disorder	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

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Sirukumab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ustekinumab	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Minocycline	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Methotrexate	C	Unknown	Not Reported
Orencia	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15923770	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2653534-00		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Amino	Humira			S	Subcutaneous			Not Reported
transferase Increased; Arthralgia; Aspartate	Actemra			S	Unknown			Not Reported
Amino	Actemra			S	Unknown			Not Reported
transferase Increased; Basal Cell Carcinoma; Blood	Actemra			S	Unknown			Not Reported
Parathyroid Hormone Decreased; C-Reactive Protein Increased;	Alendronate Sodium			S	Unknown			Not Reported
Contraindicated Product Administered; Drug Eruption; Drug	Apo-Leflunomide			S	Oral			Not Reported
Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased;	Codeine			S	Unknown			Not Reported
Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia;	Enbrel			S	Unknown			Not Reported
Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported



Detailed Report

Daily Activities;	Methotrexate	S	Subcutaneous	Not Reported
Musculoskeletal Stiffness;	Methotrexate	S	Subcutaneous	Not Reported
Pain; Panniculitis;	Methotrexate	S	Subcutaneous	Not Reported
Peripheral Swelling; Rash;	Methotrexate	S	Subcutaneous	Not Reported
Rash Pruritic; Red Blood	Methotrexate	S	Subcutaneous	Not Reported
Cell Sedimentation Rate	Methotrexate	S	Subcutaneous	Not Reported
Increased; Rheumatoid	Methotrexate	S	Subcutaneous	Not Reported
Arthritis; Rheumatoid	Methotrexate	S	Subcutaneous	Not Reported
Nodule; Skin Necrosis;	Methotrexate	S	Subcutaneous	Not Reported
Skin Ulcer; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Product Effect Decreased;	Methotrexate	S	Subcutaneous	Not Reported
Therapeutic Product Effect	Methotrexate	S	Subcutaneous	Not Reported
Incomplete; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Response Decreased;	Methotrexate	S	Subcutaneous	Not Reported
Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Intramuscular	Not Reported
	Sulfasalazine	S	Intramuscular	Not Reported
	Sulfasalazine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Myochrysine	S	Unknown	Not Reported
Ciclosporin	C		Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Ciclosporin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	15932948	EXPEDITED (15-DAY)		HO, LT, OT	CA-ABBVIE-19K-028-2655966-00		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Humira			S	Subcutaneous			Not Reported
Antibody Test Positive;	Humira			S				Not Reported
Arthralgia; Arthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Diarrhoea;	Anakinra			S	Subcutaneous			Not Reported
Dizziness; Drug Ineffective; Drug	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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

Intolerance; Drug Specific Antibody; Human	Enbrel	S	Subcutaneous	Not Reported
Antichimeric Antibody	Enbrel	S	Subcutaneous	Not Reported
Positive; Intentional	Hydroxychloroquine	S	Oral	Not Reported
Product Use Issue; Joint Effusion; Joint Injury;	Hydroxychloroquine	S	Oral	Not Reported
Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea;	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Obesity; Off Label Use;	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Polyarthritis; Product Use In Unapproved Indication;	Infliximab	S	Unknown	Not Reported
Psoriasis; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Septic Shock;	Methotrexate	S	Subcutaneous	Not Reported
Synovitis; Therapy Non-Responder; Underdose;	Methotrexate	S	Subcutaneous	Not Reported
Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Not Reported
	Triamcinolone	S	Intra-articular	Not Reported
	Triamcinolone	S		Not Reported
	Naproxen	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Kineret	S	Subcutaneous	Not Reported
	Kineret	S		Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Gammagard	S	Intravenous (not otherwise specified)	Not Reported

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Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Triamcinolone Acetonide	S		Not Reported
Triamcinolone Acetonide	S		Not Reported
Tocilizumab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S		Not Reported
Apo-Naproxen	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Vaccinia Immune Globulin (Immunoglobulin G Human)	S	Unknown	Not Reported
Folic Acid	C		Not Reported
Triamcinolone Hexacetonide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	16140356	EXPEDITED (15-DAY)		OT	PHHY2019CA070200		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	16403034	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2809805-00		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Humira			S	Subcutaneous			Not Reported	
	Arava			S	Oral			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Enbrel			S	Unknown	823		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Sulfasalazine			S	Subcutaneous			Not Reported	
	Apo Leflunomide			S	Unknown			Not Reported	
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Unknown			Not Reported	
	Apo-Acetaminophen			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Tylenol			S	Unknown			Not Reported	

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Doxycycline Hyclate	S	Unknown	Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Acetaminophen And Codeine Phosphate	C		Not Reported
Methotrexate	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Celebrex	C	Oral	Not Reported
Leflunomide	C		Not Reported
Codeine	C		Not Reported
Celecoxib	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	16408931	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA127221		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Voltaren			S	Unknown	Unk		Novartis
Abdominal Pain Upper;	Voltaren			S				Novartis
Abnormal Loss Of Weight;	Voltaren			S				Novartis
Adverse Drug Reaction;	Voltaren			S				Novartis
Adverse Reaction;	Diclofenac Potassium			S	Unknown			Novartis
Arthropathy; Deafness;	Diclofenac Potassium			S				Novartis
Deafness Transitory;	Diclofenac Potassium			S				Novartis
Decreased Appetite;	Diclofenac Potassium			S				Novartis
Dizziness; Drug	Diclofenac Potassium			S				Novartis
Hypersensitivity; Ear	Diclofenac			S	Unknown	Unk		Novartis
Infection; Eating Disorder;	Diclofenac			S				Novartis
Feeding Disorder;	Diclofenac			S				Novartis
Functional Gastrointestinal	Diclofenac			S				Novartis
Disorder; Gastrointestinal	Acetylsalicylic Acid Sandoz			S	Unknown	325 Mg		Not Reported
Disorder; Gastrointestinal	Acetylsalicylic Acid Sandoz			S				Not Reported
Pain; Headache;	Acetylsalicylic Acid Sandoz			S				Not Reported
Hypophagia;	Acetylsalicylic Acid Sandoz			S				Not Reported
Musculoskeletal Disorder;	Acetylsalicylic Acid Sandoz			S				Not Reported
Nausea; Off Label Use;	Vitamin C			S	Unknown			Not Reported

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Pharyngitis; Vomiting; Weight Decreased	Clopidogrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Humira	S			Not Reported
	Motrin	S	Unknown		Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Motrin	S			Not Reported
	Plaquenil	S	Oral	Unk	Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
	Aspirin	S	Oral	Unk	Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported
	Aspirin	S			Not Reported

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

Naprosyn	S	Unknown	Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Acetylsalicylic Acid W/Clopidogrel	S	Unknown	Not Reported
Apo Sulfatrim	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk Not Reported
Sulphamethoxazole	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Sulfatrim	S	Unknown	Not Reported
Tramadol Hcl	C	Unknown	Not Reported
Tramadol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	16762680	EXPEDITED (15-DAY)		OT	DE-DEXPHARM- 20190689			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported	
	Quensyl			S	Unknown			Not Reported	
	Eliquis			S		2.5 Mg Bid		Not Reported	
	Roactemra			S				Not Reported	
	Spasmolyt			S				Not Reported	
	Spasmolyt			S				Not Reported	
	Omeprazole			S	Oral	20 Mg Every 12 Hours: In The Morning And In The Evening		Not Reported	
	Ramipril			S	Oral	In The Morning And In The Evening		Not Reported	
	Volibris			S				Not Reported	
	Sildenafil Citrate			S				Not Reported	
	Lyrica			S		100 Mg, Tid		Not Reported	

FDA Adverse Event Reporting System

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Detailed Report

Pregabalin	S	1 Df, 3x/Day (1 - 1- 1)	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17271238	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-202001000259			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Dry Eye; Dry Mouth; Lower Respiratory Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Salagen			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Vimovo			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Vitamin D3			C		25 Ug		Not Reported
	Methotrexate			C		Unk		Not Reported
	Celebrex			C		Unk		Not Reported
	Arthrotec			C		Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Omega 3			C		Unk		Not Reported
	Orthotics			C				Not Reported
	Orthotics			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17488060	NON-EXPEDITED			US-PFIZER INC-2020092938		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Back Disorder; Breast Cyst; Bronchitis; Chest Pain; Condition Aggravated; Dyspnoea; Fibromyalgia; Frustration	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	[Hydroxychloroquine Sulfate] Plaquenil [Hydroxychloroquine]			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Tolerance Decreased;
Insomnia; Joint Swelling;
Malaise; Memory
Impairment;
Musculoskeletal Stiffness;
Nodule; Osteoarthritis;
Pain; Product Dose
Omission; Respiratory
Disorder; Weight
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17532940	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA067280			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Cosentyx			S	Unknown	Unk		Novartis
Anaphylactic Shock;	Leflunomide			S	Unknown	20 Mg, Unknown		Not Reported
Diarrhoea; Drug	Infliximab			S	Intravenous (not	520 Mg		Not Reported
Ineffective; Drug					otherwise specified)			
Intolerance;	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
Hypersensitivity; Nausea;	Humira			S	Subcutaneous	Unk		Not Reported
Renal Impairment;	Otezla			S	Oral	Unk		Not Reported
Synovitis	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17658870	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA- 202003001936			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17659181	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA- 202003002316			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Acute Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic), Plaquenil	S	Oral	200 Mg, Qd	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic), Plaquenil	S	Oral	200 Mg, Qd	Concordia
	Irbesartan	C		Unk	Not Reported
	Lercanidipine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17659505	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030160		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Prescribed Underdose	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17659894	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030087		52 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Milligram, Qh		Not Reported	
	Arava			S	Oral	20 Milligram, Qd		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported	
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Risedronate Sodium			S	Unknown	35 Milligram, Qwk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660024	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145583		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot	Celebrex			S	Unknown			Pfizer	
	Enbrel			S	Subcutaneous			Pfizer	
	Methotrexate Sodium			S	Unknown			Pfizer	

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

Fracture; General Physical Health Deterioration;	Methotrexate Sodium	S	Subcutaneous	20 Mg, Weekly	Pfizer
Hepatitis; Incorrect Route Of Product Administration;	Sulfasalazine	S	Oral	500 Mg, Unk	Pfizer
Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use;	Orencia	S	Unknown		Not Reported
Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	20 Mg, 1 Every 1 Day	Not Reported
	Arava	S	Unknown		Not Reported
	Prednisolone	S	Unknown		Not Reported
	Prednisone	S	Endocervical		Not Reported
	Risedronate Sodium	S	Unknown	5 Mg, Unk	Not Reported
	Actemra	S	Unknown		Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported
	Desoximetasone	C	Unknown	5 Mg, 1x/Day	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone Acetate	C	Unknown	5 Mg,1 Every 1 Day	Not Reported
	Tylenol [Paracetamol]	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660039	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145608			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Methotrexate Sodium			S	Unknown	Unk		Pfizer
Abdominal Pain; Blister;	Methotrexate Sodium			S	Unknown	12.5 Mg, Unk		Pfizer
Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth	Sulfasalazine			S	Unknown	Unk		Pfizer
	Lipitor			S	Oral			Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Arthrotec			S				Pfizer

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Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Cimzia	S		Unk	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Cosentyx	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Dovobet	C	Topical		Not Reported
	Flovent	C			Not Reported
	Folic Acid	C	Oral		Not Reported
	Multi Vitamin & Mineral	C	Oral		Not Reported
	Omeprazole	C	Oral		Not Reported
	Ventolin [Salbutamol]	C			Not Reported
	Vitamin D2	C	Oral	1000 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660080	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147592			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Myochrysine			S	Unknown			Not Reported
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147560			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Constipation; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium	S	Unknown	Pfizer
	Aralen [Chloroquine Sulfate]	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660093	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020146051			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Methotrexate Sodium			S	Oral	Unk		Pfizer	
Antinuclear Antibody Positive; Arthralgia;	Methotrexate Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer	
Arthritis; Blister; Dry Mouth; Headache;	Celebrex			S	Unknown	Unk		Pfizer	
Hypersensitivity Vasculitis;	Sulfasalazine			S	Unknown	Unk		Pfizer	
Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling;	Rituximab			S	Unknown	Unk		Not Reported	
Lymphadenopathy; Menorrhagia;	Arava			S	Unknown	Unk		Not Reported	
Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement;	Belimumab			S	Unknown	Unk		Not Reported	
Peripheral Swelling; Rheumatoid Arthritis;	Breo Ellipta			S	Respiratory (inhalation)	Unk		Not Reported	
Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Colchicine			S	Unknown			Not Reported	
	Dexilant			S	Oral	60 Mg, 1x/Day		Not Reported	
	Estrojel			S	Topical	Unk Unk, 1x/Day		Not Reported	
	Meloxicam			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 2x/Day		Not Reported	
	Prednisone			S	Unknown	50 Mg, Unk		Not Reported	
	Ventolin Hfa			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660317	NON-EXPEDITED			US-PFIZER INC-2020147388		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Azithromycin			S		Unk		Pfizer	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147922			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Polyarthrits; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate Sodium			S		Unk		Pfizer	
	Remicade			S		Unk		Not Reported	
	Aralen Hydrochloride			S		Unk		Not Reported	
	Humira			S		Unk		Not Reported	
	Leflunomide			S		Unk		Not Reported	
	Myochrysine			S		Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661320	DIRECT	Y	OT			40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Electrocardiogram Qt Prolonged; Transaminases Increased	Hydroxychloroquine			S	Oral			Not Reported	
	Lopinavir/Ritonavir			S	Oral			Not Reported	
	Azithromycin			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661328	DIRECT	Y	OT			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Hydroxychloroquine			S	Oral				Not Reported
	Lopinavir/Ritonavir			S					Not Reported
	Atorvastatin 80mg			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661548	EXPEDITED (15-DAY)		OT	NVSC2020CA096823		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Neoral			S	Oral	Unk			Novartis
	Neoral			S	Subcutaneous	Unk			Novartis
	Rituximab			S	Unknown	Unk			Not Reported
	Leflunomide			S	Oral	20 Mg, Qd			Not Reported
	Methotrexate Disodium			S	Subcutaneous	25 Mg, Qw			Not Reported
	Methotrexate Disodium			S	Oral	20 Mg, Qw			Not Reported
	Ciclosporin Sandoz			S	Subcutaneous	Unk			Novartis
	Adalimumab			S	Subcutaneous	40 Mg			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk			Not Reported
	Apo-Hydroxyquine			S	Oral	Unk			Not Reported
	Apo-Leflunomide			S	Oral	Unk, Qd			Not Reported
	Apo-Leflunomide			S	Unknown	Unk			Not Reported
	Apo-Leflunomide			S	Subcutaneous	Unk			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q2w			Not Reported
	Enbrel			S	Unknown	Unk			Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w			Not Reported

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

Hydroxychloroquine	S	Oral	20 Mg	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	20 Mg, Bid	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Orencia	S	Unknown	75 Mg, Qmo	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Avara	C	Oral	20 Mg, Qd	Not Reported
Rituxan	C	Unknown	500 Mg, Qd	Not Reported
Cimzia	C	Subcutaneous	200 Mg, Q2w	Not Reported
Risedronate	C	Oral	25 Mg, Qw	Not Reported
Risedronate	C	Oral	30 Mg, Qw	Not Reported
Plaquenil	C	Oral	200 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661837	EXPEDITED (15-DAY)		OT	NVSC2020CA097860		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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

Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Ciclosporin Sandoz	S	Unknown		Novartis
Sulfasalazine	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Every 1 Week	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661903	DIRECT	Y	LT			47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Plaquenil			S				Not Reported	
	Azithromycin Tablet			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662028	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA-202003002623			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dependence; Off Label Use	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd, Coated Tablet		Concordia	
	Puran T4			C		Unk		Not Reported	
	Pregabalin			C		50 Mg		Not Reported	

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

Pregabalin	C	Not Reported
Pregabalin	C	Not Reported
Pregabalin	C	Not Reported
Alektos	C	Not Reported

20 Mg

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662053	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1223033		54 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral	Unknown Dosage		Not Reported
	Plaquenil			S	Oral	800 Mg		Not Reported
	Augmentin			C	Oral	Unknown Dosage		Not Reported
	Hypnovel			C				Not Reported
	Sufentanil			C				Not Reported
	Etomidate			C				Not Reported
	Tracrium			C				Not Reported
	Esmeron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662107	EXPEDITED (15-DAY)		OT	NVSC2020CA097244		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Neoral			S	Oral	Unk		Novartis
	Neoral			S	Subcutaneous	Unk		Novartis
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported
Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported	

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

Humira	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	C	Oral	5 Mg, Qd (2 Every 1 Days)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662141	EXPEDITED (15-DAY)		OT	FR-ADVANS PHARMA-202003002380			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Hydroxychloroquine			S	Oral	400 Mg, Qd (Fiim-Coated Tablet)		Concordia	
	Enoxaparin			C		Unk		Not Reported	
	Paracetamol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662227	EXPEDITED (15-DAY)		OT	CA-ADVANS PHARMA-202003002617			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cutaneous Lupus Erythematosus; Stress	Hydroxychloroquine			S	Unknown	Unk		Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662417	EXPEDITED (15-DAY)		OT	US-ADVANS PHARMA-202003003386			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Zinc Salt Nos			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662684	EXPEDITED (15-DAY)		OT	NVSC2020US098481			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retinopathy	Hydroxychloroquine			S	Unknown	(1.2-8.3) Mg/Kg		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662798	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1222453		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Cardiomyopathy	Hydroxychloroquine			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663000	EXPEDITED (15-DAY)		OT	NVSC2020CA098112			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Dactylitis; Drug Ineffective; Enthesopathy; Inflammation; Joint Stiffness; Psoriasis; Psoriatic Arthropathy; Tenosynovitis; Vertigo	Cosentyx			S	Unknown	300 Mg, Qmo		Novartis	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Prednisone			C	Oral	10 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663200	EXPEDITED (15-DAY)		HO, OT	FR-ADVANSZ PHARMA-202003002813			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film-Coated Tablet)		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663224	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202003002823			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
	Nivaquine			S	Unknown	1 Dosage Form, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663282	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202004002844			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Fall; Femur Fracture; Hypoacusis; Intentional Product Use Issue; Product Dose Omission; Unevaluable Event	Hydroxychloroquine			S	Unknown	2cp/Day, Qd		Concordia	
	Hydroxychloroquine			S		1cp/Day For 15		Concordia	
	Cardensiel			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663302	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202004002921			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Arava			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663508	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3361937-00			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Kaletra 200/50			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663522	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362044-00			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Kaletra 200/50			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663539	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056-3362011-00			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Kaletra 200/50			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17665337	DIRECT	Y	OT			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged;	Hydroxychloroquine Oral Tablet			S	Oral			Not Reported	
Transaminases Increased	Lopinavir/Ritonavir			S	Oral			Not Reported	
	Atorvastatin 40mg			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17665521	DIRECT	Y	DE, HO			79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Test Positive	Hydroxychloroquine 200mg Po			S	Oral			Actavis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	11925949	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ABBVIE-15K-028-1444053-00			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint	Enbrel			S	Subcutaneous			Not Reported
Arthroplasty; Joint Swelling; Joint Swelling;	Enbrel			S				Not Reported
Knee Arthroplasty; Myocardial Infarction; Myocardial Infarction;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Near Death Experience; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Orencia			S				Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Gold			S				Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

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

Increased; Renal Failure;	Hydroxychloroquine	S		Not Reported
Sepsis; Stent Placement;	Methotrexate	S	Intra-arterial	Not Reported
Stomatitis; Terminal State;	Methotrexate	S		Not Reported
Thrombosis; Urticaria	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Hydroxyquine	S		Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Medical Marijuana	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Kineret	C		Not Reported
	Rituximab	C		Not Reported
	Kineret	C	Unknown	Not Reported

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

Lyrica	C	Unknown		Not Reported
Ilaris	C	Subcutaneous	Single-Use Vial	Not Reported
Rituximab W/Urelumab	C	Unknown		Not Reported
Anakinra	C	Unknown		Not Reported
Urelumab	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	14144042	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020346		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Spinal Stenosis; Synovitis	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Unk		Not Reported
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported

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

Orencia	S	Intravenous (not otherwise specified)	500 Mg, Once Every Four Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk 1 Every 4 Months	Not Reported
Orencia	S	Unknown	500 Unk, Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	14243063	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021705			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Winpred			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

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

Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	14404773	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005233			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown	Unk		Apotex
Alopecia; Exposure During	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
Pregnancy; Glossodynia;	Folic Acid			S	Unknown	Unk		Not Reported
Hip Arthroplasty; Knee	Prednisone			S	Unknown	Unk		Not Reported
Arthroplasty; Maternal	Hydroxychloroquine			S	Unknown	Unk		Apotex
Exposure During	Actemra			S	Unknown	Unk		Not Reported
Pregnancy; Pain;								
Pemphigus; Rheumatoid								

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

Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	14558788	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2262991-00			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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

Leflunomide	S	Unknown	Not Reported
Gold	S	Other	Not Reported
Plaquenil	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	15132896	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018014806			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 Milligram, Qd, 40 [Mg/D]; 0-13.6 Gestational Week		Macleods
	Pantoprazole			S	Transplacental	Unk		Macleods
	Aspirin			S	Transplacental	100 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Aspirin			S	Transplacental	Unk		Not Reported
	Prednisolone			S	Transplacental	10 Milligram, Bid, Tablet, From Gestational Week 0-14		Not Reported
	Simvastatin			S	Transplacental	Unk		Not Reported
	Simvastatin			S	Transplacental	Unk, Tablet, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	6 Milligram, Qd, From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	Unk, 1 Trimester		Not Reported
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported
	Heparins, Low-Molecular-Mass			S	Transplacental	Unk		Not Reported

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

Salbutamol Sulfate	S	Transplacental	Unk Unk, Qd, From Gestational Week 0-14	Not Reported
Salbutamol Sulfate	S	Transplacental	Unk	Not Reported
Metamizole Sodium	S	Transplacental	Unk	Not Reported
Metamizole Sodium	S	Transplacental	Unk,From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	Unk	Not Reported
Nicotine	S	Transplacental	Unk, From Gestational Week 0-14	Not Reported
Ramipril	S	Transplacental	20 Milligram, From Gestational Week 0-13+6 Weeks) Maternal Dose 20 Mg	Not Reported
Hydroxychloroquine	S	Transplacental	400 Milligram, Qd, From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental	300 Milligram, Qd, 300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Rivaroxaban	S	Transplacental	Unk	Not Reported
Ezetimibe	S	Transplacental	Unk, Tablet, From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	Unk	Not Reported
Torasemide	S	Transplacental	100 Mg Qd From Gestational Week 0-14	Not Reported
Xarelto	S	Transplacental	Unk, Film Coated Tablet,From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Milligram, Qd, 2 X 100	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptual,	Not Reported

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

				Trimester: Preconceptional	
Rasilez	S	Unknown			Not Reported
Enoxaparin Sodium	S	Transplacental	Unk, From Gestational Week 0-14		Not Reported
Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd		Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First; Probably Only In Hospital In Week 5		Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week		Not Reported
Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week		Not Reported
Cyclophosphamide	C	Transplacental	Unk, 3000 [Mg Cumulative]; Preconceptional		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	15337014	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019548		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness;	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk, Therapy Duration: 59		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Meloxicam			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	160 Mg, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Mobicox			S	Unknown	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported

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

Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	80 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	15622524	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557260-00		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Diclofenac			C				Not Reported
	Desoximetasone			C	Oral			Not Reported

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

Xeljanz	C	Subcutaneous	Not Reported
Zostavax	C	Subcutaneous	Not Reported
Methotrexate	C		Not Reported
Voltaren	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	15629606	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555539-00		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Cough; Diarrhoea; Diarrhoea; Drug Ineffective; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported

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

Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	15670302	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2571378-00		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Humira			S	Subcutaneous			Not Reported
	Mefenamic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Forms		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S				Not Reported
Sulfasalazine			S	Unknown			Not Reported	
Plaquenil			S	Oral			Not Reported	
Plaquenil			S				Not Reported	

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

Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Tylenol	C	Unknown	Not Reported
Advil	C		Not Reported
Dequalinium Chloride	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	15806693	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2618205-00		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
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Personal Independence In	Methotrexate	S	Oral		Not Reported
Daily Activities;	Methotrexate	S	Oral		Not Reported
Panniculitis; Peripheral	Methotrexate	S	Oral		Not Reported
Swelling; Rash; Rash	Methotrexate	S	Oral		Not Reported
Pruritic; Red Blood Cell	Methotrexate	S	Oral		Not Reported
Sedimentation Rate	Methotrexate	S	Oral		Not Reported
Increased; Rheumatoid	Methotrexate	S	Oral		Not Reported
Arthritis; Rheumatoid	Methotrexate	S	Oral		Not Reported
Nodule; Skin Necrosis;	Methotrexate	S	Oral		Not Reported
Skin Ulcer; Therapeutic	Methotrexate	S	Oral		Not Reported
Response Decreased;	Methotrexate	S	Oral		Not Reported
Ulcer	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Myochrysine	S	Parenteral	Foa-Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Foa-Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported

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

Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Etanercept	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Codeine Sulfate	S	Unknown	Not Reported
Prednisone	C		Not Reported
Xeljanz	C		Not Reported
Ciclosporin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	16079861	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2019-06082		41 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug	Infliximab			S	Unknown	Unknown		Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Etanercept			S	Unknown	Unknown		Not Reported
	Etanercept			S				Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Apremilast			S	Oral			Not Reported
	Apremilast			S	Unknown	Unknown		Not Reported
	Apremilast			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

Eruption; Drug	Certolizumab Pegol	S	Subcutaneous	Unknown	Not Reported
Hypersensitivity; Drug	Ciclosporin	S	Oral	Unknown	Not Reported
Ineffective; Drug	Ciclosporin	S	Subcutaneous	Unknown	Not Reported
Intolerance; Enthesopathy;	Cimzia	S	Subcutaneous	Unknown (Solution), Single Use Pre-Filled Syringe	Not Reported
Erythema; Fatigue;					
General Physical Health					
Deterioration; Granuloma					
Skin; Headache; Hepatic					
Enzyme Increased;	Enbrel	S	Subcutaneous		Not Reported
Hypercalcaemia;	Enbrel	S	Unknown	Unknown	Not Reported
Hypersensitivity; Infection;	Enbrel	S			Not Reported
Inflammation; Infusion	Humira	S	Subcutaneous	Unknown (Solution)	Not Reported
Related Reaction; Loss Of					
Personal Independence In	Golimumab	S	Subcutaneous	Unknown	Not Reported
Daily Activities; Mobility					
Decreased; Mucosal	Motrin	S	Oral		Not Reported
Inflammation; Nausea; Off	Motrin	S	Unknown		Not Reported
Label Use; Pain;	Orencia	S	Subcutaneous	Unknown	Not Reported
Panniculitis; Peripheral	Orencia	S	Unknown	Unknown	Not Reported
Swelling; Psoriatic					
Arthropathy; Rash; Rash	Otezla	S	Oral		Not Reported
Pruritic; Red Blood Cell					
Sedimentation Rate;	Otezla	S	Unknown	Unknown	Not Reported
Rheumatoid Arthritis;	Otezla	S			Not Reported
Rheumatoid Nodule; Skin	Simponi	S	Subcutaneous	Unknown (Solution)	Not Reported
Necrosis; Skin Ulcer;					
Synovitis; Tendonitis;	Stelara	S	Subcutaneous	Unknown (Solution)	Not Reported
Tenosynovitis; Therapy	Sulfasalazine	S	Unknown		Not Reported
Non-Responder; Tongue					
Disorder; Treatment	Sulfasalazine	S	Unknown	Unknown	Not Reported
Failure; Ulcer	Ustekinumab	S	Subcutaneous	Unknown	Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Oral		Not Reported
	Ibuprofen	S	Unknown		Not Reported
	Leflunomide	S	Oral	Unknown	Not Reported
	Sulfamethoxazole	S	Oral		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Apo-Cyclosporine	S	Oral	Unknown	Not Reported

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

Codeine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Tocilizumab	S	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown	Unknown	Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Oral	Unknown	Not Reported
Methotrexate	C	Unknown	Unknown	Not Reported
Mogadon	C	Unknown		Not Reported
Nitrazepam	C	Oral		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Oxyneo	C	Unknown		Not Reported
Oxyneo	C	Unknown	(Extended Release)	Not Reported
Uloric	C	Oral		Not Reported
Benadryl	C	Unknown	Unknown	Not Reported
Dexilant	C	Unknown	Unknown (Delayed Release)	Not Reported
Dexilant	C	Unknown	Unknown, Prolonged Release	Not Reported
Gravol	C	Unknown	Unknown	Not Reported
Oxycodone	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported

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

Acide Folique	C	Unknown	Unknown	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Prednisone	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	16589246	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2851920-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone Gold			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	16954774	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2972637-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain;	Humira			S	Subcutaneous			Not Reported
	Plantago Afra			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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

Pain In Extremity; Rash;
Syncope; Vomiting

Plaquenil	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Morphine	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Aclasta	S	Intravenous (not otherwise specified)	Not Reported
Morphine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Hydrochlorothiazide	C		Not Reported
Ergocalciferol	C		Not Reported
Folic Acid	C		Not Reported
Cannabis Sativa	C		Not Reported
Tums	C		Not Reported
Lipitor	C		Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Calcium Carbonate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17223484	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3215049-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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

Actemra	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Bupropion	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Simponi	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17543919	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA072124		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Cosentyx			S	Unknown	Unk		Novartis
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk Unk, Bid		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unknown		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Mg, Bid		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40.0 Mg, Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Unknown		Not Reported

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

Hydroxychloroquine	S	Unknown	400 Mg, Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Mg, Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Endocervical	400 Mg	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	2 Df, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Insulin	C	Oral	Unk (Drops)	Not Reported
Metformin	C	Unknown	2 Df, Bid	Not Reported
Metformin	C	Unknown	1 Unk	Not Reported
Plaquenil	C	Unknown		Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17552068	EXPEDITED (15-DAY)		HO, OT	JP- GLAXOSMITHKLINE- JP2020JPN044468		40 YR	Female	JPN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cytomegalovirus Infection	Belimumab			S	Intravenous drip	Unk		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks		Glaxosmithkline
	Belimumab			S	Intravenous drip	10 Mg/Kg, Once In Every Four Weeks		Glaxosmithkline
	Prednisolone			S	Oral	Unk		Glaxosmithkline
	Prednisolone			S	Oral	10 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	9 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	8 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	7 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	6 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	7 Mg, 1d		Glaxosmithkline
	Prednisolone			S	Oral	8 Mg, 1d		Glaxosmithkline
	Tacrolimus			S	Unknown	Unk		Glaxosmithkline
	Imuran			S	Unknown	Unk		Glaxosmithkline
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Bonoteo			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Bayaspirin			C		Unk		Not Reported
	Rebamipide			C		Unk		Not Reported
	Baktar			C		Unk		Not Reported
	Colonel			C		Unk		Not Reported
	Loxofen (Loxoprofen Sodium)			C		Unk		Not Reported
	Amerge			C		Unk		Not Reported
	Sumilu Stick			C		Unk		Not Reported
	Celecox			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17572131	EXPEDITED (15-DAY)		OT	CA-JNJFOC-		63 YR	Male	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

20200332786

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diverticulitis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S				Not Reported
	Arava			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/ Sulfasalazine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17594562	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332781		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil /00072602/ Sulfasalazine			S	Oral			Not Reported
				S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17605651	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332787		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17605666	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332776		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Adverse Drug Reaction; Drug Ineffective; Dyspepsia; General Physical Health	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Stelara			S	Subcutaneous			Janssen

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

Deterioration; Nausea; Rheumatoid Arthritis; Sleep Disorder	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Minocycline Hydrochloride	S		Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17636246	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000165			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Cardiac	Tacrolimus			S	Transplacental			Panacea Biotec
Septal Defect; Congenital	Tacrolimus			S	Transplacental			Panacea Biotec
Cardiovascular Anomaly;	Tacrolimus			S	Transplacental			Panacea Biotec
Foetal Exposure During	Rivaroxaban			S	Transplacental			Not Reported
Pregnancy; Foetal	Rivaroxaban			S	Transplacental			Not Reported
Exposure During	Nicotine			S	Transplacental			Not Reported
Pregnancy; Heart Disease								
Congenital; Truncus								
Arteriosus Persistent;								

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

Ventricular Septal Defect	Simvastatin	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Acetylsalicylic Acid	S	Transplacental	Not Reported
	Pantoprazole	S	Transplacental	Not Reported
	Pantoprazole	S	Transplacental	Not Reported
	Torsemide	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Ramipril	S	Transplacental	Not Reported
	Aliskiren	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Prednisolone	S	Transplacental	Not Reported
	Dipyrene	S	Transplacental	Not Reported
	Dipyrene	S	Transplacental	Not Reported
	Hydroxychloroquine Sulfate	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Heparin	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Salbutamol Sulfate	S	Transplacental	Not Reported
	Ezetimibe	S	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17656876	EXPEDITED (15-DAY)	LT		US-PFIZER INC-2020148479		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Azithromycin			S	Oral	500 Mg, Daily (500 Mg On Day 1)		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily (Followed By 250 Mg Daily For 4 Days)		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day (400 Mg Twice Daily On Day 1)		Not Reported

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

	Hydroxychloroquine	S	Oral	400 Mg, 1x/Day (Followed By 400 Mg Daily For 4 Days)	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17663632	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018207		52 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo	
	Azithromycin			S				Aurobindo	
	Paracetamol			S	Oral	1 Gram, 3 Times A Day (1gr Cada 8 Horas)		Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day (Dia)		Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported	
	Dolquine			S				Not Reported	
	Simvastatina Alter			S	Oral	0-0-1		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17663750	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201706-003792			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Apoleflunomide			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	

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

Rheumatoid Arthritis; Treatment Failure	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Xeljanz	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17663778	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020147529		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Enbrel			S	Subcutaneous	40 Mg, Weekly		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	Unk		Pfizer
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Monthly		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Endocervical	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	0.75 Mg, Monthly		Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17663950	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021948		53 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Hypersensitivity	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Apremilast			S	Unknown	30 Mg, Bid		Not Reported	
	Methotrexate Sodium			S	Oral	30 Mg, Q.Wk.		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Otezla			S	Unknown	30 Mg, Bid		Not Reported	
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17664171	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1698			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deformity; Movement Disorder; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Myochrysine			S	Unknown			Not Reported	
	Aralen			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17664175	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1694			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthritis; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased; Renal Impairment	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17664213	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144- 3361763-00		95 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Kaletra 200/50			S	Oral			Not Reported	
	Quetiapina			S	Oral			Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported	
	Hidroxicloroquina Sulfato			S	Oral			Not Reported	
	Risperidona			S	Oral			Not Reported	
	Losartan			C	Oral			Not Reported	
	Clindamicina Hidrocloruro			C	Intravenous (not otherwise specified)			Not Reported	
	Lorazepam			C	Oral			Not Reported	
	Furosemda			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17664281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION			Unknown	CAN

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Detailed Report

PHARMA-TREX2020-1710

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Polyarthrititis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17664285	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1705			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neuropathy Peripheral	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Codeine Phosphate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil S			S	Unknown			Not Reported
	Azathioprine Sodium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17664555	EXPEDITED (15-DAY)		OT	HK-ACCORD-178663		67 YR	Female	HKG

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Tuberculosis	Methotrexate			S				Accord
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Tocilizumab			S				Not Reported
	Tofacitinib			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17665208	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020145791		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Xeljanz			S	Unknown	Unk		Pfizer
	Enbrel			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Subcutaneous	162 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Calcium/Vitamin D3			C		Unk		Not Reported
	Hydrocortisone			C		Unk Unk, 2x/Day		Not Reported
	Pantoloc [Pantoprazole]			C		Unk		Not Reported
	Prednisone			C		20 Mg, 1x/Day		Not Reported
	Tylenol Arthritis Pain			C		2 Df, 2x/Day		Not Reported
	Xarelto			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17665668	NON-EXPEDITED		HO, OT	NVSC2020US099010		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Prednisone			S	Unknown	5 Mg, Qd		Novartis

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Chest Pain; Cough; Decreased Appetite; Dyspnoea; Hepatitis Viral; Nausea; Pyrexia	Hydroxychloroquine Metronidazole	S C	Unknown Oral	200 Mg, Bid Unk	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17665946	EXPEDITED (15-DAY)		DE, HO, OT	SK-HORIZON-PRE-0109-2020		57 YR	Male	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Prednisone Azathioprine Hydroxychloroquine Cyclosporine A Methotrexate Belimumab Cyclophosphamide Mycophenolate Mofetil			S S S S S S S S				Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17666426	EXPEDITED (15-DAY)		OT	NVSC2020PT099374		48 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Detachment Of Retinal Pigment Epithelium	Hydroxychloroquine			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17667117	EXPEDITED (15-DAY)		OT	NVSC2020CA098733			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Arthritis; Bone Erosion; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis;	Cosentyx Rituximab			S S	Unknown Intravenous (not otherwise specified)	Unk Unk		Novartis Not Reported

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

Foot Deformity; Hepatic Cirrhosis; Joint Dislocation; Joint Stiffness; Off Label Use; Osteoarthritis; Osteoporosis; Synovitis	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Oral	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Otezla	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sirukumab	S	Unknown	Unk	Not Reported
	Stelara	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Dilaudid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17667548	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2375555-00		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Arthralgia; Drug	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
Ineffective; Drug	Certolizumab	S	Unknown	Not Reported
Ineffective; Drug	Otezla	S	Unknown	Not Reported
Ineffective; Drug	Golimumab	S	Unknown	Not Reported
Ineffective; Drug	Infliximab	S	Unknown	Not Reported
Ineffective; Inflammation;	Methotrexate	S	Unknown	Not Reported
Joint Swelling;	Leflunomide	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine	S	Unknown	Not Reported
Red Blood Cell	Sulfasalazine	C		Not Reported
Sedimentation Rate	Xeljanz	C		Not Reported
Abnormal; Rheumatoid	Leucovorin Calcium	C		Not Reported
Arthritis; Therapeutic	Codeine	C		Not Reported
Product Effect Decreased;	Ibuprofen	C		Not Reported
Therapeutic Product Effect	Dilaudid	C		Not Reported
Decreased	Plaquenil	C		Not Reported
	Acetaminophen	C		Not Reported
	Ventolin Hfa	C		Not Reported
	Nexium Dr	C		Not Reported
	Advair Diskus	C		Not Reported
	Allopurinol	C		Not Reported
	Cyclobenzaprine Hcl	C		Not Reported
	Atrovent Hfa	C		Not Reported
	Hydromorphone Hcl	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17667774	EXPEDITED (15-DAY)		OT	NVSC2020CA098830			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Colitis;	Cosentyx			S	Unknown	150 Mg, Unknown		Novartis
Drug Ineffective; Drug	Methotrexate			S	Oral	15 Mg, Unknown		Not Reported
Intolerance; Intestinal	Actemra			S	Unknown	Unk		Not Reported
Polyp; Joint Swelling;	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
Leukopenia; Nausea;	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Unknown		Not Reported
Nephrolithiasis; Off Label	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
Use; Pain; Pain In								
Extremity; Peripheral								
Swelling; Product Dose								

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

Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate Orencia Otezla Sulfasalazine	S S S C	Unknown Subcutaneous Oral Unknown	400 Mg, Unknown 125 Mg, Unknown 30 Mg, Bid 1 G, Bid	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17667856	EXPEDITED (15-DAY)		OT	NVSC2020CA098863		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Cosentyx			S	Unknown	Unk		Novartis
	Rituximab			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported
	Morphine			C	Topical	Unk		Not Reported
	Methotrexate			C	Oral	1 Df, Qw		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17668265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2020-017705			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028- 3362555-00			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Humira			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Aralen			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17668434	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030217		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Event; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Abatacept			S	Unknown	Unk		Bristol Myers Squibb	
	Apo-Leflunomide			S	Oral	10 Milligram		Not Reported	
	Cefazolin			S	Unknown	Unk		Not Reported	
	Certolizumab Pegol			S	Subcutaneous	400 Milligram, 1 Every 2 Weeks, Duration 1 Days And 15 Days		Not Reported	
	Certolizumab Pegol			S	Subcutaneous	200 Milligram, 1 Every 2 Weeks, Duration 2.0 Years		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, 2 Every 1 Days		Not Reported	
	Leflunomide			S	Oral	10 Milligram, Duration 2 Months		Not Reported	
	Methotrexate			S	Subcutaneous	25 Milligram, 1 Every 1 Week, Duration 2 Months		Not Reported	

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Plaquenil S	S	Unknown	200 Milligram, 2 Every 1 Days	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Amlodipine	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	5 Milligram, 2 Every 1 Days	Not Reported
Viread	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17668438	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-017975		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Product Use In Unapproved Indication	Clindamycin			S	Unknown	300 Milligram, Two Times A Day		Aurobindo	
	Rifampin			S	Unknown	600 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day (Monday Through Friday)		Not Reported	
	Clobetasol			S	Unknown	Unk Unk, Two Times A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17669671	DIRECT					54 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angiopathy; Anxiety; Burning Sensation; Fatigue; Muscle Spasms; Nervous System Disorder; Nonspecific Reaction; Pain Of Skin; Pruritus	Hydroxychloroquine Sulfate Plaquenil			S	Oral	Quantity:1 Tablet(S);	4 DAY	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	8792714	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-009507513- 1209DEU004039			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Simvastatin			S	Transplacental	Unk		Merck	
	Simvastatin			S	Transplacental	From Gestational Week 0- 14		Merck	
	Viemmm 10 Mg Tabletten			S	Transplacental	From Gestational Week 0- 14		Merck	
	Aspirin			S	Transplacental	From Gestational Week 0- 14		Not Reported	
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported	
	Prednisolone			S	Transplacental	From Gestational Week 0- 14		Not Reported	
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0- 14		Not Reported	
	Albuterol			S	Transplacental	From Gestational Week 0- 14		Not Reported	
	Torseמידe			S	Transplacental	From Gestational Week 0- 14		Not Reported	
	Novaminsulfon			S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5		Not Reported	
Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Not Reported		

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Dipyrrone	S	Transplacental	From Gestational Week 0-14	Not Reported
Ramipril	S	Transplacental	20 Mg Unk From Gestational Week 0-113+6	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin Sodium	S	Transplacental	Unk	Not Reported
Heparin	S	Transplacental	Unk	Not Reported
Clexane (Enoxaparin Sodium)	S	Transplacental	200 Mg/D (2x100)	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	13059562	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015791		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Back Disorder; Condition	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	

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

Aggravated; Contraindicated Product	Leflunomide	S	Oral	20 Mg, Qd	Apotex
Administered; Cutaneous	Hydroxychloroquine	S	Unknown	200 Mg, Unk	Apotex
Vasculitis; Drug	Hydroxychloroquine	S	Unknown	200 Mg, Qd	Apotex
Ineffective; Drug	Apo-Leflunomide	S	Oral	20 Mg, Qd	Apotex
Intolerance; Infiltration	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Anaesthesia; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash;	Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Rheumatoid Arthritis;	Anakinra	S	Subcutaneous	100 Mg, Qd	Not Reported
Rheumatoid Factor	Anakinra	S	Subcutaneous	100 Mg, Unk	Not Reported
Positive; Secretion	Anakinra	S	Subcutaneous	Unk	Not Reported
Discharge; Spinal	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Stenosis; Spinal Stenosis;	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Synovitis; Vasculitic Rash	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.,	Not Reported
	Humira	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Humira	S	Unknown	40 Mg, Cyclical	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.,	Not Reported
	Humira	S	Subcutaneous	40 Mg, Cyclical	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.O.Wk.	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Unk, Once Every 4 Weeks	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported

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

Orencia	S	Unknown	500 Mg, Cyclical	Not Reported
Orencia	S	Intravenous (not otherwise specified)	500 Mg, Cyclical	Not Reported
Kineret	S	Subcutaneous	100 Mg, Qd	Not Reported
Methotrexate Sodium	S	Oral	12.5 Mg, Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	13059788	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015748		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

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Ilaris	C	Unknown		Not Reported
Plaquenil /00072602/	C	Unknown	Unk	Not Reported
Rituximab	C			Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	14235439	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021912			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Rheumatoid Arthritis; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Abatacept			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Infliximab			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Morphine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	15391128	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-955090		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral			Actavis	
	Perindopril			S	Oral			Not Reported	
	Perindopril			S	Unknown			Not Reported	
	Plaquenil			S	Oral	200 Mg/ Day		Not Reported	
	Cortancyl			S	Oral	20 Milligram Daily; 10-20µg		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	15625329	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558387-00		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Duration:365.0		Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			C	Endocervical			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	15760613	NON-EXPEDITED			US-PFIZER INC-2018522861		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Hypersensitivity	Heparin Sodium	S		Unk	Pfizer
	Lisinopril	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Duloxetine	S	Oral	100 Mg, Daily	Not Reported
	Insulin	C		Unk	Not Reported
	Januvia	C		Unk	Not Reported
	Metformin	C		Unk	Not Reported
	Losartan/Hctz	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	15819449	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-DRREDDYS-GER/GER/19/0106738			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Ezetimibe			S	Transplacental			Not Reported
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	20 Mg Unk From Gestational Week 0-113+6		Not Reported
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Torsemide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Not Reported
	Salbutamol			S	Transplacental	From Gestational Week 0-14		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5 082(Film Coated Tablet)		Not Reported

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Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Heparin (Salt Not Specified)	S	Transplacental	Unk Unk,Unk	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Enoxaparin Sodium	S	Transplacental	200 Mg/D (2x100)	Not Reported
Rituximab	S	Transplacental	Last Time In December 2011: Pre Or Periconceptional	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Heparin Lmw	S	Transplacental	Unk	Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	15933671	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2656078-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Female; Condition Aggravated;	Humira			S	Subcutaneous			Not Reported	

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

Contraindicated Product Administered; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Gold	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	C			Not Reported
	Meloxicam	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	16972574	EXPEDITED (15-DAY)		DE, OT	CA-ABBVIE-19K-028-2978585-00		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain;	Humira			S	Subcutaneous			Not Reported	
	Humira			S				Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S				Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Sulfasalazine			S				Not Reported	
	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Sodium Aurothiomalate			S				Not Reported	

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

Pulmonary Embolism;	Rituxan	S	Unknown	Not Reported
Pulmonary Thrombosis;	Rituxan	S		Not Reported
Red Blood Cell	Rituximab	S	Unknown	Not Reported
Sedimentation Rate				
Increased; Renal Failure;	Rituximab	S		Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Unknown	Not Reported
Rheumatoid Factor	Leflunomide	S	Unknown	Not Reported
Positive; Sepsis; Synovitis;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Terminal State;				
Thrombosis	Doxycycline Hyclate	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Simponi	C	Unknown	Not Reported
	Rituximab W/Urelumab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17182091	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019231676			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
Alopecia; Arthropathy;	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
Contraindicated Product	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
Administered; Discomfort;	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline
Drug Ineffective; Exposure								
During Pregnancy;	Cetirizine Hydrochloride +			S	Unknown	Unk		Glaxosmithkline
Fatigue; Glossodynia;	Pseudoephedrine Hydrochloride							
Hand Deformity; Off Label	Cetirizine Hydrochloride +			S	Unknown	Unk		Glaxosmithkline
Use; Pain; Pemphigus;	Pseudoephedrine Hydrochloride							
Product Use Issue; Rash;	Desoximetasone			S	Oral	Unk		Glaxosmithkline
Rheumatoid Arthritis;								
Swelling; Systemic Lupus	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
Erythematous; Wound	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline

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Cimzia (Certolizumab Pegol)	S	Subcutaneous	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Milligram Solution	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Solution	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram Solution	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil (Hydroxychloroquine)	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17422218	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-04558		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S				Not Reported
	Celebrex			S	Unknown	Unknown		Not Reported
	Celebrex			S	Unknown			Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Celecoxib			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown			Not Reported

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Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous	Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Unknown	Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Atorvastatin Calcium	C	Oral		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Cipralext (Escitalopram)	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Conjugated Estrogens	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Gabapentin	C	Unknown		Not Reported
Gabapentin	C	Oral		Not Reported

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

	Hydrochlorothiazide	C	Unknown		Not Reported
	Hydromorphone Hydrochloride	C	Oral		Not Reported
	Hydromorphone Hydrochloride	C	Oral		Not Reported
	Mupirocin	C	Topical	Unknown	Not Reported
	Pantoloc (Pantoprazole)	C	Unknown		Not Reported
	Shark Liver Oil	C	Unknown	Unknown	Not Reported
	Tapentadol Hydrochloride	C	Unknown		Not Reported
	Taro-Mupirocin	C	Topical	Unknown	Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported
	Tramadol Hydrochloride	C			Not Reported
	Tramacet	C	Oral		Not Reported
	Tramacet	C			Not Reported

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15-Apr-2020	17631825	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200337612			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Keratitis	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17643631	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-015943			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Dermatitis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo

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Bullous; Drug Reaction With Eosinophilia And Systemic Symptoms; Pemphigus; Stevens- Johnson Syndrome; Toxic Epidermal Necrolysis	Aciclovir	S	Unknown	Unk	Aurobindo
	Cefixime	S	Unknown	Unk	Aurobindo
	Ceftriaxone	S	Unknown	Unk	Aurobindo
	Fluconazole	S	Unknown	Unk	Aurobindo
	Gentamicin	S	Unknown	Unk	Not Reported
	Lamotrigine	S	Unknown	Unk	Aurobindo
	Metronidazole	S	Unknown	Unk	Aurobindo
	Paracetamol	S	Unknown	Unk	Aurobindo
	Risperidone	S		Unk	Aurobindo
	Terbinafine	S	Unknown	Unk	Aurobindo
	Ampicillin;Sulbactam	S	Unknown	Unk	Not Reported
	Ketoprofen	S	Unknown	Unk	Not Reported
	Clarithromycin	S	Unknown	Unk	Not Reported
	Aspirin	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Vancomycin	S	Unknown	Unk	Not Reported
	Enoxaparin	S	Unknown	Unk	Not Reported
	Ceftazidime	S	Unknown	Unk	Not Reported
	Oxacillin	S	Unknown	Unk	Not Reported
	Clindamycin	S	Unknown	Unk	Not Reported
	Carbamazepine	S	Unknown	Unk	Not Reported
	Phenytoin	S	Unknown	Unk	Not Reported
	Phenobarbital	S	Unknown	Unk	Not Reported
	Teicoplanin	S	Unknown	Unk	Not Reported
	Rufinamide	S	Unknown	Unk	Not Reported
	Cotrimoxazole	S	Unknown	Unk	Not Reported
	Cisplatin	S	Unknown	Unk	Not Reported
	Fluorouracil	S	Unknown	Unk	Not Reported
	Asa	S	Unknown	Unk	Not Reported

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Lithium	S	Unknown	Unk	Not Reported
Methylphenidate	S	Unknown	Unk	Not Reported
Acetylcysteine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17647577	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403510		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Discomfort; Drug Ineffective; Hyperaesthesia; Memory Impairment; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Cimzia			C	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Folic Acid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17648818	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE-IT2020061361		43 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Belimumab			S	Unknown	Unk		Glaxosmithkline
	Tacrolimus			S	Unknown	Unk Unk, Qd		Glaxosmithkline
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	12.5 Mg, Qd		Not Reported

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Prednisone	S	Unknown	15 Mg, Qd	Not Reported
Prednisone	S	Unknown	15 Mg, Qd	Not Reported
Prednisone	S	Unknown	7.5 Mg, Qd	Not Reported
Prednisone	S	Unknown	10 Mg, Qd	Not Reported
Prednisone	S	Unknown	50 Mg, Qd	Not Reported
Prednisone	S	Unknown	25 Mg, Qd	Not Reported
Hydroxychloroquine Sulfate	S		400 Mg, Qd	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk, Qd	Not Reported
Rituximab	C	Unknown	Unk	Not Reported
Methylprednisolone	C	Unknown	Unk (Pulses)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17668607	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030971		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Orencia			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Desoximetasone			C	Unknown	10 Milligram, Qd		Not Reported
	Diclofenac			C	Unknown	100 Milligram, Qd		Not Reported

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Methotrexate	C	Unknown		Not Reported
Voltaren [Diclofenac Sodium]	C	Unknown	100 Milligram, Qd	Not Reported
Xeljanz	C	Unknown		Not Reported
Zostavax	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17668861	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1720		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock;	Methotrexate (Trade Name			S	Unknown			Not Reported
Arthralgia; Bedridden;	Unknown)							
Condition Aggravated;	Methotrexate (Trade Name			S	Subcutaneous			Not Reported
Drug Ineffective;	Unknown)							
Fibromyalgia; Foot	Celebrex			S	Unknown			Not Reported
Fracture; General Physical	Enbrel			S	Subcutaneous			Not Reported
Health Deterioration;								
Hepatitis; Loss Of	Sulfasalazine			S	Oral			Not Reported
Personal Independence In	Orencia			S	Unknown			Not Reported
Daily Activities; Lower								
Limb Fracture; Mobility	Cimzia			S	Subcutaneous			Not Reported
Decreased; Myocardial	Simponi			S	Subcutaneous			Not Reported
Infarction; Off Label Use;								
Osteoporosis; Rheumatoid	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Arthritis; Therapeutic	Plaquenil			S	Unknown			Not Reported
Product Effect Incomplete;	Apo-Leflunomide			S	Oral			Not Reported
Treatment Failure								
	Arava			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Endocervical			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported

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Leflunomide	C	Unknown	Not Reported
Prednisone Acetate	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17668878	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1723			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling Abnormal; Gastrointestinal Disorder; Hepatic Enzyme Abnormal; Inappropriate Schedule Of Product Administration; Mouth Haemorrhage; Mouth Ulceration; Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Methotrexate (Trade Name Unknown) Methotrexate (Trade Name Unknown) Sulfasalazine Lipitor Enbrel Arthrotec Cimzia Cosentyx Cosentyx Humira Leflunomide Plaquenil Dovobet Flovent Folic Acid Multi Vitamins & Minerals Omeprazole Ventolin Vitamin D2			S S S S S S S S S S S S S C C C C C C C C	Unknown Unknown Unknown Oral Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17668879	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1721		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Endocervical			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17668886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1730			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Musculoskeletal Stiffness;	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not			Not Reported	

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Polyarthrits; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Aralen Hydrochloride	S	otherwise specified)	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Plaquenil	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669411	EXPEDITED (15-DAY)		HO	GR-TEVA-2020-GR-1222919		56 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pyrexia; Urinary Tract Infection; Urinary Tract Pain	Ciclosporin			S	Oral	50 Mg, 2x/Day		Ivax
	Hydroxychloroquine Phosphate			S	Oral	200 Mg, 1x/Day		Not Reported
	Medrol			S	Oral	4 Mg, 1x/Day		Not Reported
	Thyrohormone			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669462	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-031059			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Codeine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported
	Arava			C	Unknown	20 Milligram, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669590	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096477			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Treatment Failure	Plaquenil			S				Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C		20 Mg, Qd		Not Reported
	Tylenol Arthritis Pain			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096338			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fracture; Infection; Pneumonia	Arava			S	Oral			Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown	5 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	1.0 Df, Qw		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669592	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096116			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Retinal Injury	Plaquenil			S				Sanofi	
	Arava			S				Sanofi	
	Humira			C				Not Reported	
	Methotrexate			C		Unk		Not Reported	
	Xeljanz			C				Not Reported	
	Sulfasalazine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669596	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA096531		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Congestive; Hypertensive Heart Disease; Peripheral Swelling; Therapeutic Response Changed	Plaquenil			S		200 Mg, Bid		Sanofi	
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported	
	Arava			S	Oral	20 Mg		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669689	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1037212		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported	
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported	
	Acetaminophen			C	Unknown	6 Gram		Mylan	
	Metronidazole			C	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669899	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009850			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure Via Breast Milk	Leflunomide			S	Transmammary	Unk		Apotex	
	Hydroxychloroquine			S	Transmammary	Unk		Apotex	
	Methotrexate			S	Transmammary	Unk		Not Reported	
	Enbrel			S	Transmammary	Unk		Not Reported	
	Certolizumab Pegol			S	Transmammary	Unk		Not Reported	
	Prednisone			C	Transmammary	Unk		Not Reported	
	Sulfasalazine			C	Transmammary	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669916	DIRECT		DE				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S				Not Reported	
	Hydroxychloroquine			S			1 DAY	Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S			2 DAY	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670426	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2020-NL-1222817		31 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Pre-Eclampsia; Premature Delivery	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis	
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Actavis	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Teva	
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q2w		Not Reported	
	Omeprazole			C	Oral	20 Milligram Daily;		Not Reported	
	Novorapid			C	Subcutaneous	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sudden Death	Levofloxacin (2791a)			S	Unknown			Teva	
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Lopinavir+Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported	
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported	
	Prednisona (886a)			C	Oral	20 Mg		Not Reported	
	Ceftriaxona (501a)			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671067	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096278			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Plaquenil			S				Sanofi	
	Hydroxychloroquine Sulfate			S				Sanofi	
	Arava			S				Sanofi	
	Cetirizine Hydrochloride			S				Not Reported	
	Folic Acid			S				Not Reported	
	Alendronate Sodium			S				Not Reported	
	Methotrexate			S				Not Reported	
	Prednisone			S				Not Reported	
	Sulfasalazine			S				Not Reported	
	Actemra			S				Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671115	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096445			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Fatigue; Malaise	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S	Unknown			Sanofi
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Prednisone			S		1 Df, Qw		Not Reported
	Prevacid			C				Not Reported
	Risedronate Sodium			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671152	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223013		63 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Hidroxicloroquina (2143a)			S	Oral	2-5 Day: 200mg / 12h		Teva
	Hidroxicloroquina (2143a)			S	Oral	1 Day: 400mg / 12h, 2-5 Day: 200mg / 12h		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500mg/24h		Not Reported

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Azitromicina (7019a)	S							Not Reported
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h					Not Reported
Ceftriaxona (501a)	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671318	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020-12495			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; C-Reactive Protein Increased;	Infliximab			S	Unknown	Unknown		Not Reported
Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion;	Adalimumab			S	Subcutaneous			Not Reported
Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use In Unapproved Indication; Product Use Issue; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Etanercept			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Sulfasalazine			S	Unknown	Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17672057	NON-EXPEDITED			US-CELGENEUS-USA-20200403202		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Otezla			S	Oral	60 Milligram		Celgene	
	Plaquenil			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17672078	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1221322			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Flutter	Hydroxychloroquine Sulfate Watson			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17672447	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-12513			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Etanercept			S	Unknown	Unknown		Not Reported	
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported	
	Cimzia			S	Subcutaneous	Unknown, Single Use Pre-Filled Syringe Solution Subcutaneous		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	
	Methotrexate			S	Unknown	Unknown		Not Reported	
	Orencia			S	Unknown	Unknown		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported	

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Simponi	S	Subcutaneous	Unknown	Not Reported
Tocilizumab	S	Unknown	Unknown	Not Reported
Azathioprine	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17672893	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3363203-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported
Abdominal Pain; Blister;	Cosentyx			S	Unknown			Not Reported
Drug Ineffective; Feeling	Leflunomide			S	Unknown			Not Reported
Abnormal; Gastrointestinal	Methotrexate			S	Unknown			Not Reported
Disorder; Hepatic Enzyme	Plaquenil			S	Unknown			Not Reported
Abnormal; Inappropriate	Sulfasalazine			S	Unknown			Not Reported
Schedule Of Product	Enbrel			S	Unknown			Not Reported
Administration; Mouth	Cimzia			S	Unknown			Not Reported
Haemorrhage; Mouth	Arthrotec			S	Unknown			Not Reported
Ulceration;	Lipitor			S	Oral			Not Reported
Musculoskeletal	Dovobet			C	Topical			Not Reported
Discomfort; Nausea;	Folic Acid			C	Oral			Not Reported
Psoriatic Arthropathy;	Omeprazole			C	Oral			Not Reported
Pyrexia; Synovitis	Flovent			C	Respiratory (inhalation)			Not Reported
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Vitamin D2			C	Oral			Not Reported
	Multi Vitamin			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17673591	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096533			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Pneumonitis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S		Unk		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pneumococcal Vaccine Polysacch 23v			C	Unknown			Not Reported
	Prevna 13			C	Intramuscular			Not Reported
	Varicella Zoster Vaccine Live			C	Unknown			Not Reported
	Xeljanz			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17673602	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030963		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; C- Reactive Protein Increased; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Orencia			S	Endocervical			Bristol Myers Squibb
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown	1 Gram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17673612	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020153377			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Methotrexate Sodium			S	Unknown	15 Mg, Unk		Pfizer	
	Etanercept			S	Subcutaneous	50 Mg, Weekly		Pfizer	
	Arava			S	Unknown	20 Mg, 1x/Day		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17673774	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004002881			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Malaise; Systemic Lupus Erythematosis Rash	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17673830	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202003002619			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Inflammation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674032	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018904		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported	
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674037	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018903		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674055	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018905		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Dolquine			S	Other	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674074	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031130			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Orencia			S	Endocervical			Bristol Myers Squibb	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous	Unk, Qwk		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Mefenamic Acid			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Prednisone	C	Oral 10 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674075	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018907		28 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Azithromycin			S	Oral	500 Milligram, Once A Day		Not Reported	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17675095	DIRECT	Y	DE			88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Pulmonary Embolism; Unresponsive To Stimuli	Hydroxychloroquine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	12776522	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-024854		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qmo		Bristol Myers Squibb	
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	4 Mg/Kg, Unk		Not Reported	
	Actemra			S	Unknown	40 Milligram/Kilogram		Not Reported	
	Actemra			S	Unknown	4 Milligram		Not Reported	
	Arava			S	Oral	10 Mg, Qd		Not Reported	
	Apo-Hydroxyquine			S	Unknown	200 Mg, Unk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported	
	Humira			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Cyclical		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported	
	Methotrexate			S	Unknown	25 Mg, Qwk		Not Reported	
	Methotrexate			S	Unknown	250 Milligram, Qwk		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported	
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid		Not Reported	
	Apo-Prednisone			S	Unknown	Unk		Not Reported	

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

Methotrexate Sodium	S	Unknown		Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
Prevacid	C	Unknown	30 Mg, Bid	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	50 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	14409544	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP005298		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Potassium			S	Unknown	Unk		Apotex
Abdominal Pain Upper;	Hydroxychloroquine			S	Unknown	Unk		Apotex
Abnormal Loss Of Weight;	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
Adverse Drug Reaction;	Arava			S	Oral	Unk		Not Reported
Adverse Reaction;	Enbrel			S	Subcutaneous	Unk		Not Reported
Arthropathy; Deafness;	Humira			S	Subcutaneous	Unk		Not Reported
Deafness Transitory;	Methotrexate Sodium			S	Unknown	Unk		Not Reported
Decreased Appetite;	Motrin			S	Unknown	Unk		Not Reported
Dizziness; Drug	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
Hypersensitivity; Ear	Plaquenil /00072602/			S	Oral	Unk		Not Reported
Infection; Feeding	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
Disorder; Foot Operation;	Voltaren /00372301/			S	Unknown	Unk		Not Reported
Functional Gastrointestinal	Sulfamethoxazole			S	Unknown	Unk		Not Reported
Disorder; Gastrointestinal	W/Trimethoprim							
Disorder; Gastrointestinal	Gold			S	Unknown	Unk		Not Reported
Pain; Headache;	Tramadol Hcl			C	Unknown	Unk		Not Reported
Hypophagia;								
Musculoskeletal Disorder;								
Nausea; Pharyngitis;								
Shoulder Arthroplasty;								
Vomiting; Weight								
Decreased								

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	14933830	EXPEDITED (15-DAY)		DS, OT	GB-SA-2018SA139931		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S				Sanofi
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Erythromycin			S				Sanofi
	Arava			S				Sanofi
	Demerol			S				Sanofi
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported
	Methotrexate			S	Oral	1 Df, Qw		Not Reported
	Metronidazole			S				Sanofi
	Norfloxacin			S				Not Reported
	Cefaclor			S				Not Reported
	Erythromycin			S				Sanofi
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Pregabalin			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			S	Unknown			Not Reported
	Erythromycin Estolate			S		Unk		Not Reported
	Levofloxacin			S				Not Reported
	Arthrotec			S				Not Reported
	Meperidine Hydrochloride			S				Not Reported
	Plaquenil			S				Sanofi
	Norfloxacin			S			400 Mg	Not Reported
	Celecoxib			S	Oral		200 Mg	Not Reported
	Celecoxib			S	Oral		200 Mg, Qd	Not Reported
	Prednisone			S				Not Reported
	Bisoprolol Fumarate			S				Not Reported
	Bisoprolol Salt Not Specified			S				Not Reported
	Humira			S	Subcutaneous	400 Mg		Not Reported
Diclofenac Sodium/Misoprostol			S				Not Reported	
Methotrexate Sodium			S				Not Reported	
Pethidine Hydrochloride			S				Sanofi	
Sulfasalazine			S			500 Mg	Not Reported	

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

Levofloxacin Hemihydrate				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	15621514	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557370-00		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Apo Hydroxyquine			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	16205860	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039198		70 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Eye Disorder; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Metformin Hydrochloride			S	Unknown	1000 Milligram Daily;		Actavis
	Desoximetasone			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Altace			C	Unknown	5 Milligram Daily;		Not Reported
	Asa			C	Unknown	81 Milligram Daily;		Not Reported
	D-Alpha Tocopherol/Fish Oil			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Oral	15 Milligram Daily;		Not Reported
	Rosuvastatin Calcium			C	Unknown	20 Milligram Daily;		Not Reported
	Vitamin D /00107901/			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	16582688	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028- 2852957-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Joint Swelling; Ocular Toxicity; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported

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

Plaquenil	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Indocid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	16844994	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019378939		59 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S		Unk		Pfizer
	Lansoprazole			S	Unknown	Unk		Pfizer
	Ramipril			S	Unknown	Unk		Pfizer
	Prednisolone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported
	Thyroxine			S	Unknown	Unk		Not Reported
	Thyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Metformin Hydrochloride			S		Unk		Not Reported
	Levothyroxine Sodium			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17180775	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019054476		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abdominal Discomfort; Adverse Drug Reaction;	Cimzia	S	Subcutaneous		Ucb
Alopecia; Anti-Cyclic Citruillinated Peptide	Cimzia	S			Ucb
Antibody Positive;	Cetirizine Hydrochloride	S		10 Milligram	Not Reported
Arthralgia; Arthropathy;	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Blood Cholesterol Increased; Condition	Cetirizine Hydrochloride	S			Not Reported
Aggravated;	Cetirizine Hydrochloride	S		10 Milligram	Ucb
Contraindicated Product Administered; Decreased Appetite; Discomfort; Drug Ineffective; Drug	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S		Unk	Not Reported
Intolerance; Fatigue; General Physical Health Deterioration;	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S			Not Reported
Glossodynia; Hand Deformity; Headache;	Plaquenil [Hydroxychloroquine Sulfate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Hepatic Enzyme Increased; Hip	Remicade	S	Intravenous (not otherwise specified)	400 Milligram, Weekly (Qw)	Not Reported
Arthroplasty;	Simponi	S	Subcutaneous	50 Milligram, Monthly (Qm)	Not Reported
Hypersensitivity;	Simponi	S	Subcutaneous		Not Reported
Hypertension;	Simponi	S		Solution And Suspension For Injection In Pre-Filled Syringe	Not Reported
Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Knee	Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arthroplasty; Malaise;	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Maternal Exposure During Pregnancy; Mobility Decreased;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Musculoskeletal Stiffness;					
Off Label Use; Pain;	Humira	S	Subcutaneous	Solution	Ucb
Pemphigus; Pericarditis;	Orencia	S		Unk	Not Reported
Product Use Issue; Rash;	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rheumatic Fever;					
Rheumatoid Arthritis;					
Rheumatoid Factor Positive; Swelling; Swollen	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Joint Count Increased;	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
Synovitis; Systemic Lupus Erythematousus;	Apo Prednison	S			Not Reported
Therapeutic Product Effect	Apo Prednison	S		Unk	Not Reported

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

Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Arava	S	Oral		Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Folic Acid	S		1 Milligram	Not Reported
	Folic Acid	S		5 Milligram	Not Reported
	Folic Acid	S		0.5 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Methotrexate	S		20 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S		20 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Prednisone	S			Not Reported
	Pseudoephedrine Hcl	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
	Rituxan	S	Subcutaneous	Solution	Not Reported
	Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
	Sulfathalidine	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Phosphate	S		400 Milligram, Once Daily (Qd)	Not Reported

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

Tocilizumab	S	Subcutaneous		Not Reported
Etanercept	S		Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Winpred	S	Oral		Not Reported
Paracetamol	S			Not Reported
Stelara	S			Not Reported
Diclofenac Sodium	S			Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Topicort Lp	S	Oral		Not Reported
Sarilumab	S			Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Apo-Hydroxyquine	S			Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral		Not Reported
Otezla	S	Oral		Not Reported
Reactine [Cetirizine Hydrochloride]	S			Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Desoximetasone	S	Oral		Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous		Not Reported
Methotrexate	C	Subcutaneous		Not Reported
Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported
Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Not Reported
Diclofenac	C		50 Milligram, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17302274	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA014510		60 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Leflunomide			S	Unknown	Unk		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Pethidine Hydrochloride			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Sanofi
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Sanofi
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg		Not Reported
	Bisoprolol Salt Not Specified			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Sanofi
	Erythromycin			S	Unknown	Unk		Sanofi
	Erythromycin Estolate			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	400 Mg, Qd		Sanofi
	Plaquenil			S	Oral	Unk		Sanofi
	Arthrotec			S	Unknown	Unk		Not Reported

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

Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	400 Mg	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17315972	EXPEDITED (15-DAY)		OT	CA-SA-2020SA014485			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20.0 Mg, Qd (20.0 Milligram 1 Every 1 Days)		Sanofi
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
	Plaquenil			S	Unknown	200 Mg, Bid (2 Every 1 Days)		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qw		Sanofi
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg (Every 2 Weeks)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow (Once Every 2 Weeks)		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Wellbutrin			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17332071	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-01520		58 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Amino transferase	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
Increased; Alopecia; Arthralgia; Aspartate Amino transferase	Adalimumab			S	Subcutaneous			Not Reported
Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Etanercept			S	Unknown			Not Reported
Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance	Actemra			S	Unknown			Not Reported
Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown	Unknown		Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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Incomplete; Therapeutic Response Decreased; Ulcer	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
	Leflunomide	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

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

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Myochrysine	S	Intramuscular (Solution)	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Parenteral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified) Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified) Unknown (Powder For Solution Intravenous)	Not Reported
Remicade	S	Intravenous (not otherwise specified) Unknown (Powder For Solution Intravenous)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Unknown	Not Reported

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

Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Azathioprine	S	Unknown	Unknown	Not Reported
Celebrex	S	Unknown	Unknown	Not Reported
Naproxen	S	Unknown	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Unknown	Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17365657	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023782			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Alopecia; Contraindicated	Hydroxychloroquine Sulfate	S				Sanofi
Product Administered;	Prednisone	S				Not Reported
Fatigue; Glossodynia;	Folic Acid	S		5 Mg		Not Reported
Pemphigus; Systemic	Alendronate Sodium	S				Not Reported
Lupus Erythematosus	Hydroxychloroquine	S				Sanofi
	Leflunomide	S	Oral			Sanofi
	Cetirizine	S				Not Reported
	Hydrochloride/Pseudoephedrine					
	Hydrochloride					
	Methotrexate	S				Not Reported
	Arava	S				Sanofi
	Prednisone	S				Not Reported
	Sulfasalazine	S		500 Mg		Not Reported
	Actemra	S				Not Reported
	Cimzia	S	Subcutaneous			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	40 Mg		Not Reported
	Orencia	S	Subcutaneous			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Desoximetasone	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17486747	EXPEDITED (15-DAY)		OT	IT-VELOXIS PHARMACEUTICALS- 2020VELIT-000200		43 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Off Label Use	Envarsus			S	Unknown	Unk, Qd		Chiesi	
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Not Reported	

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Prednisone	S	Unknown	50 Mg Qd, Tapering Dose	Not Reported
Prednisone	S	Unknown	25 Mg, Qd	Not Reported
Prednisone	S	Unknown	25 Mg Qd, Dose Tapering	Not Reported
Prednisone	S	Unknown	15 Mg, Qd	Not Reported
Prednisone	S	Unknown	15 Mg Qd, Dose Tapering	Not Reported
Prednisone	S	Unknown	10 Mg Qd, Dose Tapering	Not Reported
Prednisone	S	Unknown	7.5 Mg Qd, Dose Tapering	Not Reported
Prednisone	S	Unknown	12.5 Mg Qd, Dose Tapering	Not Reported
Belimumab	S	Unknown	Unk	Not Reported
Belimumab	S	Unknown	Unk	Not Reported
Belimumab	S	Unknown	Unk	Not Reported
Belimumab	S	Unknown	Unk	Not Reported
Belimumab	S	Unknown	Unk	Not Reported
Immunoglobulin I.V	C		Unk	Not Reported
Rituximab	C		Unk	Not Reported
Methylprednisolone	C		Unk (Pulses)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17511082	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200240044			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Off Label Use	Stelara			S	Subcutaneous			Janssen	
	Simponi			S	Subcutaneous			Janssen	
	Cosentyx			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Otezla			S	Oral			Not Reported	

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

	Xeljanz		S	Unknown				Not Reported	
	Xeljanz		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17517037	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243788			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen	
	Stelara			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Otezla			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
Sulfasalazine			S	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17553274	NON-EXPEDITED		OT	CA-AMGEN-CANSP2019148132		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; No Adverse Event	Enbrel			S	Unknown	Unk		Amgen	
	Actemra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown	100 Milligram		Not Reported	
	Apo Prednison			S	Unknown	7 Milligram, Qd		Not Reported	
	Celebrex			S	Unknown	Unk		Not Reported	

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

Celebrex	S			Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	1 Milliliter, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	7 Milligram, Qd	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	7 Milligram, Qd	Not Reported
Celecoxib	S	Unknown	Unk	Not Reported
Celecoxib	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17558095	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316684		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Simponi			S	Subcutaneous			Janssen
Adverse Event;	Actemra			S	Unknown			Not Reported
Contraindicated Product	Arava			S	Unknown			Not Reported
Administered; Drug	Cimzia			S	Subcutaneous			Not Reported
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Extremity	Humira			S	Subcutaneous			Not Reported
Contracture; Nausea;	Leflunomide			S	Unknown			Not Reported
Pustular Psoriasis;	Methotrexate			S	Unknown			Not Reported
Rheumatoid Arthritis;	Plaquenil /00072602/			S	Unknown			Not Reported
Scar; Vomiting	Sulfasalazine			S	Unknown			Not Reported

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

Xeljanz	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Aspirin /00002701/	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17567096	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318557		59 YR	Male	CAN

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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17605625	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333276		41 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Middle Insomnia; Musculoskeletal Stiffness; Pain In Extremity; Rash	Simponi			S	Subcutaneous			Janssen	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S				Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Hydroxychloroquine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17605640	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200333287		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Toxicity; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen	
	Simponi			S				Janssen	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17648281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403508		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Headache; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Nausea; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Proteinuria; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Treatment Failure; Vasculitis; Weight Decreased	Simponi			S	Subcutaneous			Janssen
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Amitriptyline Hydrochloride			C				Not Reported
	Doxycycline			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Tobramycin			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17651850	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200316464		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Simponi	S	Subcutaneous	Janssen
	Doxycycline	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Tylenol Arthritis Pain	C	Unknown	Not Reported
	Tylenol Arthritis Pain	C		Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17658993	EXPEDITED (15-DAY)		LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-030043		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Interstitial Lung	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown			Not Reported	

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Disease; Joint Swelling;	Enbrel	S	Subcutaneous	Unk	Not Reported
Myocardial Infarction;	Enbrel	S	Unknown		Not Reported
Pain; Photosensitivity	Gold	S	Unknown	Unk	Not Reported
Reaction; Pulmonary	Gold	S	Unknown		Not Reported
Embolism; Pulmonary	Humira	S	Subcutaneous	Unk	Not Reported
Thrombosis; Red Blood	Humira	S	Unknown		Not Reported
Cell Sedimentation Rate	Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Increased; Renal Failure;	Hydroxychloroquine	S	Unknown		Not Reported
Sepsis; Stomatitis;	Ilaris	S	Subcutaneous	Unk	Not Reported
Terminal State;	Ilaris	S	Unknown		Not Reported
Thrombosis; Urticaria	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomida	S	Unknown	Unk	Not Reported
	Marijuana	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Minocycline	S	Unknown	Unk	Not Reported
	Oxycodone	S	Unknown	10 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported

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Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17670489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1222995		71 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia; Hypocoagulable State	Hydroxychloroquine			S	Oral	400 Milligram Daily; 200 Mg/12h		Teva	
	Kaletra			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17673141	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031084			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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Mobicox			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17673245	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018502		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Propofol			S	Intravenous (not otherwise specified)	6.6 Milligram/Kilogram, 1 In Hour, (Sedation)		Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17673960	NON-EXPEDITED			US-AMGEN-USASP2020061784		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S	Unknown	Unk		Amgen	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674049	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001167			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy; Dyspnoea Exertional	Hydroxychloroquine			S	Unknown	Unk		Ipca	

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16-Apr-2020	17674369	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096501			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Hepatotoxicity; Liver Function Test Increased	Hydroxychloroquine			S				Sanofi
	Colchicine			S				Not Reported
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S				Not Reported
	Methylprednisolone			S				Not Reported
	Sulfasalazine			S				Not Reported
	Azathioprine			S		150 Mg, Qd		Not Reported
	Bromocriptin Ct			S				Not Reported
	Ciclosporin			S				Not Reported
	Dilaudid			S				Not Reported
	Doxycycline Hyclate			S				Not Reported
	Enbrel			S				Not Reported
	Gold			S				Not Reported
	Humira			S		40 Mg		Not Reported
	Mercaptopurin			S				Not Reported
	Pamidronate Disodium			S				Not Reported
	Tenoxicam			S				Not Reported
	Ustekinumab			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674370	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097034			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Spinal Compression Fracture	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Xeljanz			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674433	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020154341		48 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia; Overdose	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Tacrolimus Monohydrate			S	Oral	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	
	Pentasa			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674454	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365014-00		36 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S				Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Azitromicina			S				Not Reported	
	Dolquine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674455	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3365006-00		72 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S				Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported	
	Ceftriaxona			S				Not Reported	
	Hidroxicloroquina			S	Oral			Not Reported	
	Hidroxicloroquina			S				Not Reported	

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16-Apr-2020	17674480	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365040-00		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S				Not Reported	
	Interferon Beta-1b			S	Subcutaneous			Not Reported	
	Interferon Beta-1b			S				Not Reported	
	Dolquine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674601	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222314			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Gout; Hypertension; Palpitations	Metformin			S	Unknown			Actavis	
	Sumatriptan Succinate			S	Unknown			Teva	
	Colchicine			S	Unknown			Not Reported	
	Januvia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674602	EXPEDITED (15-DAY)		DE	CA-TEVA-2020-CA-1222322		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort	Metformin			S	Unknown	1000 Milligram Daily;		Actavis	
	Alendronate Sodium			S	Unknown			Actavis	
	Prednisone			S	Unknown			Actavis	
	Furosemide			S	Unknown			Not Reported	
	Flovent			S	Unknown			Not Reported	
	Ipratropium Bromide/Salbutamol			S	Unknown			Not Reported	

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Sulfide				
Lipitor	S	Unknown		Not Reported
Losec [Omeprazole]	S	Unknown		Not Reported
Nitrazadon	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Salmeterol Xinafoate	S	Unknown		Not Reported
Tylenol[Paracetamol]	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674609	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-243893		45 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mycobacterium Marinum Infection	Hydroxychloroquine			S	Unknown	Unk		Sun
	Methotrexate			S	Unknown	Unk		Sun
	Prednisolone			S	Unknown	20 Milligram, Unk		Taro
	Prednisolone			S	Unknown	40 Milligram, Daily		Taro
	Sulfasalazine			S	Unknown	Unk		Sun
	Leflunomide			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674739	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1222306		28 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anovulatory Cycle; Bronchitis; Drug Ineffective; Gait Inability; Haemorrhage; Hepatic Cirrhosis; Hepatic Enzyme Increased; Impaired Work Ability; Joint Range Of Motion Decreased;	Metformin Hydrochloride			S	Unknown			Actavis
	Metformin Hydrochloride			S				Actavis
	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Warfarin Sodium			S	Unknown			Not Reported

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Malaise; Nasopharyngitis; Nausea; Off Label Use; Product Use In Unapproved Indication; Thrombosis; Uterine Disorder	Cymbalta Rituximab Xarelto Azathioprine Methotrexate	S S C C C	Unknown Intravenous (not otherwise specified) Unknown Unknown Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674823	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1741		32 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Methotrexate (Trade Name Unknown) Xeljanz Enbrel Actemra Humira Orencia Hydroxychloroquine Sulfate Leflunomide Calcium/Vitamin D3 Hydrocortisone Pantoloc Prednisone Xarelto Tylenol Arthritis Pain			S S S S S S S S C C C C C C	Unknown Unknown Unknown Subcutaneous Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674993	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2020M1036998		45 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Granuloma Skin; Mycobacterium Marinum Infection	Methotrexate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Mylan	
	Prednisolone			S	Unknown	Low-Dose		Mylan	
	Prednisolone			S	Unknown	20 Milligram(Dose Was Increased To 40mg Daily)		Mylan	
	Sulfasalazine			S	Unknown			Mylan	
	Hydroxychloroquine			S	Unknown			Mylan	
	Metoprolol			C	Unknown			Mylan	
	Amlodipine			C	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675107	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020153341			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate Sodium			S	Unknown	10 Mg, Weekly		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer	
	Etanercept			S	Unknown			Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675138	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020153374			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Constipation; Drug	Methotrexate Sodium			S	Unknown			Pfizer	

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Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Arava	C	Unknown	20 Mg, 1x/Day	Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675164	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2607481-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dizziness; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pms Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675304	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-010799			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Graft Versus Host Disease In Skin	Prednisolone			S	Unknown			Bausch And Lomb
	Ciclosporin			S	Unknown			Not Reported

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	Ibrutinib	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sirolimus	S	Unknown	Not Reported
	Bactrim Ds	C		Not Reported
	Quetiapine	C		Not Reported
	Valaciclovir	C		Not Reported
	Lamotrigine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223716		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h,		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Comp/12h, 2 Dosage Forms		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675600	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096344		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Alopecia; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Liver Function Test Increased; Loss Of Personal Independence In Daily	Plaquenil			S				Sanofi	
	Leflunomide			S		20 Mg		Sanofi	
	Sulfasalazine			S		1 G		Not Reported	
	Leflunomide			S		20 Mg		Sanofi	
	Methotrexate			S		25 Mg		Not Reported	

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Activities; Ovarian Cyst;	Certolizumab Pegol	S				Not Reported
Pain; Rheumatoid Arthritis;	Enbrel	S	Subcutaneous			Not Reported
Sleep Disorder Due To	Humira	S	Subcutaneous			Not Reported
General Medical						
Condition, Insomnia Type;	Hydroxyquinoline Sulfate	S				Not Reported
Stress; Transplant	Neoral	S				Not Reported
Dysfunction; Transplant	Rapamune	S				Not Reported
Rejection	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus	S	Oral	2 Mg, Q12h		Not Reported
	Tacrolimus	S	Oral	3 Mg, Q12h		Not Reported
	Imuran [Azathioprine]	C		25 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675601	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096537		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
Intolerance; Non-	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
Hodgkin'S Lymphoma	Minocycline Hydrochloride			S				Not Reported
	Arava			S	Oral			Sanofi
	Sulfasalazine			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Enbrel			S				Not Reported
	Azathioprine			S		100 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Amoxil [Amoxicillin]			C				Not Reported
	Leflunomide			C				Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			C				Not Reported
	Bcg Vaccine			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096830		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Laboratory Test Abnormal	Hydroxychloroquine Sulfate			S				Sanofi	
	Leflunomide			S		20 Mg, Qd (Every 1 Days)		Sanofi	
	Methotrexate			S				Not Reported	
	Actemra			S				Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Folic Acid			C				Not Reported	
	Hyzaar			C				Not Reported	
	Venlafaxine Hydrochloride			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675748	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096669		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Gastrointestinal Disorder; Inflammation; Insomnia; Nodule; Pain In Extremity; Pollakiuria; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi	
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown	10 Mg		Sanofi	
	Leflunomide			S	Unknown	20 Mg		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675757	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096873			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi	
	Arava			S	Oral	20 Mg		Sanofi	

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Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Actemra	S			Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	C	Oral	5 Mg	Not Reported
	Leflunomide	C			Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675841	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096882		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Paracetamol			S		Unk		Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Leflunomide			C		20 Mg, Qd		Not Reported

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Meloxicam	C	Unk	Not Reported
Methotrexate	C	Unk Unk, Qw	Not Reported
Synthroid	C	Unk	Not Reported

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16-Apr-2020	17675867	EXPEDITED (15-DAY)		OT	NVSC2020DE099946		45 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterium Marinum Infection	Methotrexate			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Novartis	
	Metoprolol			C	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675975	EXPEDITED (15-DAY)		OT	CA-SA-2020SA097036		71 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Hydroxychloroquine Sulfate			S				Sanofi	
	Leflunomide			S				Sanofi	
	Sulfasalazine			S				Not Reported	
	Adalimumab			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676188	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1038560		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Headache; Palpitations	Risedronate			S	Oral	35 Milligram, Total		Not Reported	
	Cortancyl			S	Oral	Unk		Mylan	
	Plaquenil /00072602/			S	Oral	1 Dosage Form, Qd		Mylan	
	Pantoprazole			C				Mylan	
	Izalgi			C				Mylan	

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Levothyrox	C								Mylan
Diffu K	C								Mylan
Atorvastatine /01326101/	C								Mylan
Clopidogrel	C								Mylan
Procoralan	C								Mylan
						Unk			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676221	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223885		43 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	2 Doses In Total		Not Reported
	Tocilizumab (8289a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676292	EXPEDITED (15-DAY)		OT	CA-SA-2020SA096405		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropod Sting; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Codeine			S				Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676418	DIRECT	Y	OT			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Hydroxychloroquine			S	Oral			Not Reported	
	Atorvastatin			S	Oral			Not Reported	
	Kaletra 200/50			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676757	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1222320			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gout; Pneumonia	Metformin			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Sulfasalazine			S	Unknown			Not Reported	
	Januvia			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Colchicine			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676812	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1224309		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycine Anhydre			S	Oral	500 Mg		Not Reported	
	Plaquenil			S	Oral	600 Mg		Not Reported	
	Ceftriaxone Base			C	Unknown			Not Reported	
	Inipomp			C	Unknown			Not Reported	

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	Rovamycine	C	Unknown	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Xarelto 10 Mg, Comprimé Pelliculé	C	Oral	Not Reported
	Diffu K	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677150	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097010		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Cellulitis; Musculoskeletal Discomfort	Plaquenil			S		Unk		Sanofi	
	Arava			S		Unk		Sanofi	
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677151	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083124		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Contraindication To Medical Treatment; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Ovarian Disorder; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Visual Impairment	Arava			S	Unknown	20 Mg		Sanofi	
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi	
	Hydroxychloroquine			S	Unknown			Sanofi	
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Actemra			S	Unknown	567 Mg, Q4w		Not Reported	

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	Rituxan	S	Unknown	Unk		Not Reported
	Celebrex	C	Unknown	Unk		Not Reported
	Inflectra [Infliximab]	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677153	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043120		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Naproxen			S	Unknown	Unk Unk,Unk		Not Reported
	Naproxen			S				Not Reported
	Naproxen Sodium			S		Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate Sodium			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	1 Df, Qm		Not Reported
	Rituximab			S				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Risedronate			C	Oral	35 Mg, Qw		Not Reported
	Arava			C	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677300	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016052		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Pain	Cimzia	S	Subcutaneous	400 Milligram, Once Daily (Qd)	Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
	Naproxen	C			Not Reported
	Hydroxyzine	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677732	EXPEDITED (15-DAY)		HO	SE-BAUSCH-BL-2020-011319		16 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Pcs		Not Reported	
	Sertraline			S	Oral			Not Reported	
	Plaquenil			S	Oral	10-15 Pcs		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677745	EXPEDITED (15-DAY)		DS, HO, OT	US-ADVANSZ PHARMA-202004002453			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronary Artery Occlusion	Hydroxychloroquine			S				Concordia	
	Prednisone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677821	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018906		95 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Levofloxacin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo	
	Risperidone			S	Oral	1 Milligram, Once A Day		Aurobindo	
	Quetiapine			S	Oral	25 Milligram, Once A Day		Aurobindo	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Two Times		Not Reported	

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	Kaletra	S	Oral	A Day		Not Reported
	Clindamycin Hydrochloride	C	Intravenous (not otherwise specified)	2 Dosage Form, Once A Day		Not Reported
	Losartan	C	Oral	600 Milligram, Four Times/Day		Not Reported
	Lorazepam	C	Oral	50 Milligram, Once A Day		Not Reported
	Furosemide	C	Oral	1 Milligram, Once A Day		Not Reported
				40 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17679795	DIRECT	Y	OT			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia	Hydroxychloroquine 200mg			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	12440760	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-042673		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
Adverse Event;	Enbrel			S	Unknown	Unk		Not Reported
Anaphylactic Reaction;	Enbrel			S	Subcutaneous	Unk		Not Reported
Arthralgia; Arthropathy;	Lyrica			S	Oral	Unk		Not Reported
Blood Glucose Increased;	Sulfasalazine			S	Unknown	1.5 Milligram, Bid		Not Reported
Condition Aggravated;	Hydroxychloroquine Phosphate			S	Unknown	Unk		Not Reported
Drug Hypersensitivity;	Simponi			S	Subcutaneous	Unk		Not Reported
Drug Ineffective; Drug	Gold			S	Unknown	Unk		Not Reported
Intolerance; Joint Swelling;	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
Lupus-Like Syndrome;	Arava			S	Oral	Unk		Not Reported
Multiple Allergies;	Arava			S	Oral	Unk		Not Reported
Musculoskeletal Pain;								
Musculoskeletal Stiffness;								
Pain; Psoriatic								
Arthropathy; Rash; Red								
Blood Cell Sedimentation								

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Rate Increased;	Actemra	S	Subcutaneous	Unk	Not Reported
Rheumatic Disorder;	Actemra	S	Unknown	Unk	Not Reported
Rheumatoid Arthritis;	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sciatica; Sinusitis;					
Swelling; Therapeutic					
Product Effect Incomplete;	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Treatment Failure; Weight Increased					
	Humira	S	Subcutaneous	40 Mg, Qwk	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Apo Mycophenolate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown		Not Reported
	Pregabalin	S	Oral		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil S	S	Oral	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Prednisone	S	Urethral	25 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Dosage Form	Not Reported
	Celecoxib	S	Oral	200 Milligram, Bid	Not Reported
	Piroxicam	C	Unknown	Unk	Not Reported
	Morphine	C	Unknown	Unk	Not Reported
	Levothyroxine	C	Unknown		Not Reported

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Methotrexate	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	12889043	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013260		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Hydroxychloroquine			S	Unknown	Unk		Apotex
Abdominal Pain Upper;	Diclofenac			S	Unknown	Unk		Apotex
Adverse Drug Reaction;	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
Adverse Reaction;	Diclofenac Potassium			S	Unknown	Unk		Apotex
Arthropathy; Deafness;	Naproxen			S	Unknown	Unk		Apotex
Deafness Transitory;	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Apotex
Decreased Appetite;	Arava			S	Oral	Unk		Not Reported
Dizziness; Drug	Arava			S	Unknown	Unk		Not Reported
Hypersensitivity; Ear	Enbrel			S	Subcutaneous	Unk		Not Reported
Infection; Eating Disorder;	Humira			S	Subcutaneous	Unk		Not Reported
Feeding Disorder; Foot	Methotrexate			S	Unknown	Unk		Not Reported
Operation; Functional	Motrin			S	Unknown	Unk		Not Reported
Gastrointestinal Disorder;	Naprosyn /00256201/			S	Unknown	Unk		Not Reported
Gastrointestinal Disorder;	Gold			S	Unknown	Unk		Not Reported
Gastrointestinal Pain;	Plaquenil /00072602/			S	Oral	Unk		Not Reported
Headache; Hypophagia;	Sodium Aurothiomalate			S	Parenteral	Unk		Not Reported
Musculoskeletal Disorder;	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
Nausea; Off Label Use;	Vitamin C /00008001/			S	Unknown	Unk		Not Reported
Pharyngitis; Shoulder	Tramadol			C	Unknown	Unk		Not Reported
Arthroplasty; Vomiting;								
Weight Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	13178489	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015826		38 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Arthritis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatic Fibrosis; Insomnia; Pain; Rash; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Apo-Venlafaxine Xr			S	Oral	150 Mg, Qd		Apotex	
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported	
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported	
	Reactine /00884302/			C	Unknown	10 Mg, Qd		Not Reported	
Effect Incomplete	Ultram /00599202/			C	Unknown	Unk		Not Reported	
	Zopiclone			C	Unknown	7.5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	13473732	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016276			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Intentional Product Use Issue; Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported	
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex	
	Hydroxychloroquine			S	Oral	Unk		Apotex	
	Prednisone			S	Oral	Unk		Not Reported	
	Prednisone			S				Not Reported	
	Apo-Prednisone			S	Unknown	Unk		Apotex	
	Diclofenac Sodium			S	Unknown	Unk		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S				Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Arava			S				Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Cimzia			S				Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
Enbrel			S				Not Reported		
Fosamax			S	Oral	Unk		Not Reported		
Fosamax			S				Not Reported		

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Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Reactine /00884302/	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S			Not Reported
Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
Methotrexate	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Plaquenil /00072602/	S			Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown	1 G, Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	13710219	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP013547		68 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Diclofenac			S	Oral	75 Mg, Bid		Apotex	
Contusion; Grip Strength	Diclofenac			S	Oral	75 Mg, Unk		Apotex	
Decreased; Joint Swelling;									

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Loss Of Personal Independence In Daily Activities; Osteoarthritis; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac	S	Oral	1 Df, Unk	Apotex
	Diclofenac	S	Oral	2 Df, Qd	Apotex
	Folic Acid	S	Unknown	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Apotex
	Lisinopril	S	Unknown	Unk	Apotex
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	200 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Oral	1 Df, Qd	Not Reported
	Prinivil	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Voltaren Sr	S	Oral	75 Mg, Bid	Not Reported
	Tecta	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	2 Df, Qd	Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Voltaren Sr	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	15020708	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0100319		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Retinal Toxicity; Toxicity To Various Agents	Docetaxel			S	Unknown	21-Day Cycles		Not Reported	
	Anastrozole			S	Unknown			Not Reported	
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	15622445	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557344-00		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Humira			S	Subcutaneous			Not Reported	
	Adalimumab			S	Unknown			Not Reported	
	Apo Sulfasalazine			S	Unknown			Not Reported	
	Apo Leflunomida			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous	Single Used Pre-Filled Syringe		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Methotrexate			S	Parenteral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown	Enteric Coated		Not Reported	
	Abatacept			S	Unknown			Not Reported	
	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	

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

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Leflunomide	S	Unknown	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Azathioprine	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Minocycline	C		Not Reported
Penicillamine	C	Unknown	Not Reported
Prednisone	C		Not Reported
Tocilizumab	C		Not Reported
Actemra	C		Not Reported
Prednisolone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	15657201	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20181128756		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Arthralgia; Coeliac Disease; Contraindicated Product Administered;	Simponi			S	Subcutaneous			Janssen
Drug Ineffective; Fatigue;	Simponi			S				Janssen
Grip Strength Decreased;	Enbrel			S	Subcutaneous			Not Reported
Headache; Injection Site Reaction; Joint Swelling;	Actemra			S	Unknown			Not Reported
Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder;	Cimzia			S	Subcutaneous			Not Reported
Onychomadesis;	Humira			S	Subcutaneous			Not Reported
Onychomycosis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

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

	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Arava	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	15839308	EXPEDITED (15-DAY)	CA, HO, OT		DE-JNJFOC-20190118228			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Anomaly; Foetal Exposure During Pregnancy; Hospitalisation; Premature Baby; Small For Dates Baby	Infliximab, Recombinant			S	Transplacental			Janssen
	Etanercept			S	Transplacental			Not Reported
	Adalimumab			S	Transplacental			Not Reported
	Certolizumab			S	Transplacental			Not Reported
	Anakinra			S	Transplacental			Not Reported
	Methotrexate			S	Transplacental			Not Reported
	Leflunomide			S	Transplacental			Not Reported
	Abatacept			S	Transplacental			Not Reported
	Tocilizumab			S	Transplacental			Not Reported
	Azathioprine			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported
	Ciclosporin			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	15839309	EXPEDITED (15-DAY)	OT		DE-JNJFOC-20190118229			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Complication Of Pregnancy; Ectopic	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen

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

Pregnancy; Foetal Death;	Etanercept	S	Unknown	Not Reported
Gestational Diabetes;	Adalimumab	S	Unknown	Not Reported
Gestational Hypertension;	Certolizumab	S	Unknown	Not Reported
Haemorrhage; Hip	Anakinra	S	Unknown	Not Reported
Arthroplasty; Paternal	Methotrexate	S	Unknown	Not Reported
Exposure During	Leflunomide	S	Unknown	Not Reported
Pregnancy; Pre-	Tocilizumab	S	Unknown	Not Reported
Eclampsia; Premature	Azathioprine	S	Unknown	Not Reported
Delivery	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	16613478	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20190721988		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Amino transferase	Remicade			S	Intravenous (not otherwise specified)			Janssen
Increased; Arthralgia; Aspartate	Simponi			S	Subcutaneous			Janssen
Amino transferase	Simponi			S				Janssen
Increased; Basal Cell Carcinoma; Blood	Stelara			S	Subcutaneous			Janssen
Parathyroid Hormone	Motrin			S	Oral			Johnson And Johnson
Decreased; C-Reactive Protein Abnormal; C-Reactive Protein	Motrin			S	Oral			Johnson And Johnson
Increased; Condition	Alendronate Sodium			S	Unknown			Not Reported
Aggravated;	Alendronate Sodium			S	Unknown			Not Reported
Contraindicated Product	Apo-Ibuprofen			S	Oral			Not Reported
Administered; Drug	Leflunomide			S	Oral			Not Reported
Eruption; Drug	Leflunomide			S	Oral			Not Reported
Hypersensitivity; Drug	Leflunomide			S	Oral			Not Reported
Ineffective; Drug								Not Reported

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

Intolerance; Drug	Leflunomide	S	Unknown	Not Reported
Tolerance Decreased;	Apremilast	S	Unknown	Not Reported
Enthesopathy; Erythema;	Apremilast	S		Not Reported
Granuloma Skin;	Apremilast	S		Not Reported
Headache;	Tocilizumab	S	Unknown	Not Reported
Hypercalcaemia;	Tocilizumab	S	Unknown	Not Reported
Hypersensitivity;	Tocilizumab	S	Unknown	Not Reported
Inflammation; Infusion	Tocilizumab	S	Unknown	Not Reported
Related Reaction; Loss Of	Sulfasalazine	S	Endocervical	Not Reported
Personal Independence In	Rituxan	S	Intravenous (not	Not Reported
Daily Activities;			otherwise specified)	
Musculoskeletal Disorder;	Rituxan	S	Intravenous (not	Not Reported
Musculoskeletal Stiffness;			otherwise specified)	
Nausea; Off Label Use;	Rituxan	S	Unknown	Not Reported
Pain; Panniculitis;	Otezla	S	Unknown	Not Reported
Peripheral Swelling;	Orencia	S	Subcutaneous	Not Reported
Product Use Issue;	Orencia	S	Intravenous (not	Not Reported
Psoriatic Arthropathy;			otherwise specified)	
Rash; Rash Pruritic; Red	Orencia	S		Not Reported
Blood Cell Sedimentation				
Rate; Red Blood Cell				
Sedimentation Rate				
Increased; Rheumatoid	Methotrexate	S	Unknown	Not Reported
Arthritis; Rheumatoid	Methotrexate	S	Subcutaneous	Not Reported
Nodule; Skin Necrosis;	Methotrexate	S	Subcutaneous	Not Reported
Skin Ulcer; Synovitis;	Methotrexate	S	Subcutaneous	Not Reported
Tendonitis; Tenosynovitis;	Methotrexate	S	Subcutaneous	Not Reported
Therapeutic Product Effect	Methotrexate	S	Subcutaneous	Not Reported
Decreased; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Product Effect Incomplete;	Methotrexate	S	Subcutaneous	Not Reported
Tongue Disorder; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported

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Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Infliximab	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S		Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Codeine	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Alendronic Acid	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Ciclosporin	S	Unknown	Not Reported
Colchicine	C	Oral	Not Reported
Febuxostat	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported

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

Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Uloric	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Nitrazepam	C	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported
Dexilant	C	Oral	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Benadryl	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	16651301	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202723			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis	Plaquenil			S	Oral	200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qw		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		15 Mg, Qw Solution		Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S		Unk		Not Reported
	Enbrel			S		25 Mg, Qow		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S		Unk		Not Reported
	Orencia			S		125 Mg		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Q6w		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported

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

Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	C		Unk	Not Reported
Wellbutrin	C		Unk	Not Reported
Xeljanz	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17114842	EXPEDITED (15-DAY)		OT	DE-TORRENT-00015319			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Unknown
	Apixaban			S		2.5 Milligram, Bid		Unknown
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Lyrica			S	Unknown	100 Milligram, Tid Capsule, Hard		Unknown
	Omeprazole			S	Oral	1 Df,2x/Day (1-0 -1)		Not Reported
	Pregabalin			S	Unknown	1 Df, Tid, 3x/Day (11-1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Unknown
	Ramipril			S	Oral	1 Df, Bid, 2x/Day (1-0-1)		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw Pre-Filled Syringe		Unknown
	Sildenafil			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Spasmolyt			S	Unknown	1 Df, 15 (Unit Unspecified), Qd (1-0-0)		Unknown
	Volibris			S	Oral	30 Milligram, Qd		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17216520	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-107050		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort;	Alendronic Acid	S	Unknown	Unk	Aurobindo
Alopecia; Contraindicated	Actemra	S	Unknown	Unk	Not Reported
Product Administered;	Arava	S	Unknown	Unk	Not Reported
Drug Ineffective;	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Hypersensitivity; Maternal	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Exposure During	Cetirizine	S	Unknown	Unk	Not Reported
Pregnancy; Pain;	Hydrochloride;Pseudoephedrine				
Pemphigus; Pericarditis;	Hydrochloride				
Product Use Issue;	Cimzia	S	Subcutaneous	Unk	Not Reported
Rheumatoid Arthritis;	Cortisone Acetate	S	Unknown	Unk	Not Reported
Systemic Lupus	Desoximetasone	S	Oral	Unk	Not Reported
Erythematosis; Treatment	Enbrel	S	Subcutaneous	Unk	Not Reported
Failure	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Once A Day	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	400 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

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

Sulfasalazine	S	Oral	1000 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17386415	EXPEDITED (15-DAY)		OT	GR-EMD SERONO-E2B_90074536		59 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Metformin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Dicumarol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17402570	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542912			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17403255	EXPEDITED (15-DAY)		OT	CA-UCBSA-2016019500			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Certolizumab Pegol Ra			S	Subcutaneous	400 Mg, Ev 2 Weeks(Qow)		Not Reported
	Certolizumab Pegol Ra			S	Subcutaneous	200 Mg, Ev 2 Weeks(Qow)		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		5 Milligram Solution		Not Reported
	Orencia			S		750 Milligram		Not Reported
	Orencia			S		750 Milligram		Not Reported

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Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Prednisone	C		50 Milligram, Once Daily (Qd)	Not Reported
Isoniazid	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17411075	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-03838		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Chest Pain; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Infliximab			S	Unknown	Unknown		Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown	Unknown		Not Reported
	Gold			S	Intramuscular	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Penicillamine			S	Unknown	Unknown		Not Reported
	Plaquenil			S	Unknown	Unknown		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Xeljanz			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Oral			Not Reported

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Azathioprine	S	Unknown	Unknown	Not Reported
Anakinra	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Unknown	Unknown	Not Reported
Azathioprine Sodium	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)	Unknown	Not Reported
Docusate Sodium	C	Oral		Not Reported
Elavil	C	Unknown	Unknown	Not Reported
Prednisone	C	Oral		Not Reported
Sulfasalazine	C	Oral		Not Reported
Sulfasalazine	C	Unknown	Unknown	Not Reported
Tobramycin	C	Unknown		Not Reported
Doxycycline	C	Oral	Unknown	Not Reported
Xeljanz	C	Unknown	Unknown	Not Reported
Elavil	C	Unknown	Unknown	Not Reported
Wellbutrin	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17535019	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1196886		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatic Steatosis	Hydroxychloroquine			S	Unknown			Teva	
	Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17583365	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		52 YR	Female	CAN

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BMS-2020-025908

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Subcutaneous	750 Milligram, Qwk		Bristol Myers Squibb
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Parenteral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	50 Milligram, 2 Every 1 Days		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17623465	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200342100			Female	CAN

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

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Prednisolone			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17628959	EXPEDITED (15-DAY)		OT	DE-ADVANSZ PHARMA-202003002234			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hallucination; Headache; Nausea	Hydroxychloroquine			S	Unknown	1 Peice Daily, Film Coated Tablet		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17656152	EXPEDITED (15-DAY)		CA, OT	FR-SA-2020SA091764			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Fluid Volume Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Premature Baby	Lovenox			S	Transplacental	1 Df, Qd		Sanofi	
	Lovenox			S	Transplacental	Unk		Sanofi	
	Plaquenil			S	Transplacental	400 Mg, Qd		Sanofi	
	Plaquenil			S	Transplacental	Unk		Sanofi	
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	1 Df, Qd		Not Reported	
	Aspegic (Acetylsalicylate Lysine)			S	Transplacental	Unk		Not Reported	
	Econazole Nitrate			S	Transplacental	300 Mg, Qd		Not Reported	
	Cortancyl			S	Transplacental	1 Df, Qd		Not Reported	
	Cortancyl			S	Transplacental	Unk		Not Reported	
	Imurel [Azathioprine]			S	Transplacental	150 Mg, Qd		Not Reported	
	Imurel [Azathioprine]			S	Transplacental	Unk		Not Reported	
	Econazole			C	Transplacental	300 Mg, Qd		Not Reported	
	Econazole			C	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678020	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030940		75 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Adalimumab			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Parenteral	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk, Qwk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	Unk Unk, Qd		Not Reported
	Ciclosporin			C	Unknown	Unk		Not Reported
	Minocycline			C	Unknown	Unk		Not Reported
	Penicillamine			C	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	6 Milligram, Bid		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678220	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016060			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Cimzia	S	Subcutaneous	Solution	Not Reported
	Actemra	S			Not Reported
	Arava	S	Oral	20 Milligram	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Once Daily (Qd)	Not Reported
	Methotrexate	S	Oral	20 Milligram, Weekly (Qw)	Not Reported
	Orencia	S			Not Reported
	Prednisone	C	Oral		Not Reported
	Leflunomide	C			Not Reported
	Folic Acid	C	Oral	5 Milligram	Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678298	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-244196		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Herpes Zoster Disseminated	Hydroxychloroquine			S	Unknown	200 Milligram, Bid, Daily		Sun
	Prednisone			S	Unknown	5 Milligram, Daily		Mutual

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678709	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020016085		64 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Dry Skin; Fatigue; Pyrexia; Rash; Weight Decreased	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678744	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1224307		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycine Dihydratee			S	Oral	500 Mg D1 Then 250 Mg Per Day		Not Reported	
	Plaquenil			S	Oral	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678760	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1777			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Drug Ineffective; Red Blood Cell Sedimentation Rate Increased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Gold/Hyoscyamus Niger/Onopordum Acanthium/Primula Veris [Homeopathic]			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678761	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1763			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	

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Etanercept	S	Subcutaneous	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678767	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3367094-00		80 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Anuria	Kaletra			S	Oral			Not Reported	
	Kaletra			S	Oral			Not Reported	
	Dolquine			S	Unknown			Not Reported	
	Dolquine			S	Unknown			Not Reported	
	Metformina			C	Oral			Not Reported	
	Lantus			C	Subcutaneous			Not Reported	
	Acovil			C	Oral			Not Reported	
	Ganfort			C	Ophthalmic			Not Reported	
	Pantoprazol			C	Oral			Not Reported	
	Paracetamol			C	Oral			Not Reported	
	Simvastatina			C	Oral			Not Reported	
	Tramadol + Paracetamol			C	Oral			Not Reported	
	Ceftriaxona			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678845	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-018482		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Aurobindo	
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported	
	Cortancyl			S	Oral	20 Milligram, Once A Day (10-20?G)		Not Reported	

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	Coversyl		S	Intracardiac	Unk				Not Reported
	Coversyl		S	Oral	Unk				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678871	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202004002655			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Upper Respiratory Tract Infection	Hydroxychloroquine Bactrim			S C				Concordia Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678919	EXPEDITED (15-DAY)		DE, OT	FR-ADVANSZ PHARMA-202004002835			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Renal Impairment; Septic Shock	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia	
	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679113	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202003002035			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679121	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202003002037			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Hydroxychloroquine			S		Unk		Concordia	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679615	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020156142			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Physical Health Deterioration; Mobility Decreased; Musculoskeletal Pain; Nervousness; Pain; Pain In Extremity	Enbrel			S	Unknown			Pfizer	
	Methotrexate Sodium			S	Subcutaneous			Pfizer	
	Sulfasalazine			S	Unknown			Pfizer	
	Ciclosporin			S	Unknown			Not Reported	
	Diclofenac Sodium			S	Oral			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Plaquenil Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679788	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA097024		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Hydroxychloroquine Sulfate			S		2 Df, Qd (Dose: 200mg)		Sanofi	
	Cefazolin			S		Unk		Not Reported	
	Leflunomide			S	Oral	10.0 Mg		Sanofi	
	Methotrexate			S	Subcutaneous	25.0 Mg, Qw		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)		Not Reported	
	Cimzia			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported	
	Rituximab			S		Unk		Not Reported	
	Enbrel			S		Unk		Not Reported	
	Orencia			S		Unk		Not Reported	
	Humira			S	Subcutaneous	Unk (Solution Subcutaneous)		Not Reported	
	Arava			C		Unk		Not Reported	

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Viread	C	Unk	Not Reported
Naproxen	C	2 Df, Qd (Dose: 500 Mg)	Not Reported
Xeljanz	C	Oral 2 Df, Qd (Dose: 5.0 Mg)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679789	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA096908		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Hydroxychloroquine Sulfate			S				Sanofi
Drug Ineffective; Fatigue;	Leflunomide			S				Sanofi
Liver Injury; Loss Of	Methotrexate			S				Not Reported
Personal Independence In	Sulfasalazine			S				Not Reported
Daily Activities; Neck Pain;	Actemra			S				Not Reported
Nodule; Pain; Pain In	Humira			S	Subcutaneous			Not Reported
Extremity; Swelling								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679976	EXPEDITED (15-DAY)		HO, OT	DE-SANOFI-AVENTIS-2012SA019610		31 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epidermal Necrosis; Lip	Cyclophosphamide			S	Unknown	Unk Unk,Unk		Not Reported
Disorder; Pigmentation	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
Disorder; Skin Lesion;	Chloroquine (Salt Not Specified)			S	Unknown	Unk Unk,Unk		Sanofi
Stevens-Johnson	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk,Unk		Not Reported
Syndrome; Toxic	Prednisolone			S	Unknown	Unk Unk,Unk		Not Reported
Epidermal Necrolysis	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680086	EXPEDITED (15-DAY)		DE, OT	FR-SGP-000004		59 YR	Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Interstitial Lung Disease; Mesenteric Vein Thrombosis; Multiple Organ Dysfunction Syndrome; Product Use In Unapproved Indication; Septic Shock	Methylprednisolone	S	Unknown			Sungen Pharma
	Methylprednisolone	S	Intravenous (not otherwise specified)			Sungen Pharma
	Prednisone	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Cyclophosphamide	S	Unknown	0.6 G/M²		Not Reported
	Cyclophosphamide	S	Unknown	0.6 G/M²		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680375	NON-EXPEDITED			US-APPCO PHARMA LLC-2082959			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness	Hydroxychloroquine Sulfate			S				Appco Pharma	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680511	NON-EXPEDITED			US-APPCO PHARMA LLC-2082963			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680526	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020- 13065		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Abnormal; C- Reactive Protein Increased; Condition	Etanercept			S	Subcutaneous	Unknown		Not Reported	
	Adalimumab			S	Subcutaneous	Unknown		Not Reported	
	Arava			S	Oral			Not Reported	

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Aggravated; Disability; Drug Hypersensitivity; Drug Ineffective; Drug- Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Ascorbic Acid	S	Unknown	Unknown	Not Reported
	Atenolol	S	Unknown		Not Reported
	Co Atenolol	S	Unknown		Not Reported
	Co Atenolol	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Ferrous Fumarate	S	Unknown	Unknown	Not Reported
	Ferrous Fumarate;Folic Acid	S	Unknown	Unknown	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	Unknown	Not Reported

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Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyn [Naproxen Sodium]	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naprosyne	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc [Pantoprazole Sodium Sesquihydrate]	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Teva Pantoprazole	S	Unknown		Not Reported

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	Vitamin C [Ascorbic Acid]	S	Unknown	Unknown	Not Reported
	Celebrex	C	Oral		Not Reported
	Celecoxib	C	Oral		Not Reported
	Prednisone	C	Unknown	Intracardiac	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680759	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003661			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retinal Disorder	Hydroxychloroquine			S		Unk			Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680864	EXPEDITED (15-DAY)		OT	NVSC2020CA096830		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Cyclosporine			S	Unknown				Novartis
	Neoral			S	Oral				Novartis
	Hydroxychloroquine Sulfate			S	Oral	20 Mg			Not Reported
	Leflunomide			S	Unknown				Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg			Not Reported
	Methotrexate Sodium			S	Oral	20 Mg			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg			Not Reported
	Remicade			S	Unknown	3 Mg/Kg			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw			Not Reported
	Orencia			S	Subcutaneous	125 Mg			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680902	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224376		46 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hepatitis Acute	Azitromicina (7019a)	S	Oral	500 Milligram Daily; 500 Mg Day	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily; 400 Mg Day	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported
	Ceftriaxona	S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680961	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099395			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Hydroxychloroquine Sulfate			S				Sanofi	
	Arava			S				Sanofi	
	Methotrexate			S				Not Reported	
	Prednisone			S				Not Reported	
	Actemra			S				Not Reported	
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported	
	Orencia			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680984	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099621			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hepatotoxicity; Rash	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi	
	Arava			S	Unknown	20 Mg, Qd		Sanofi	
	Methotrexate			S	Unknown			Not Reported	

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17-Apr-2020	17680985	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100529		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate			S				Sanofi	
	Paracetamol			S				Not Reported	
	Arava			S		200 Mg, Qd		Sanofi	
	Meloxicam			S				Not Reported	
	Methotrexate			S				Not Reported	
	Prednisone			S		5 Mg, Qd		Not Reported	
	Sulfasalazine			S				Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680986	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098964			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Urinary Tract Obstruction	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Qd		Sanofi	
	Leflunomide			S		10 Mg, 2 Every 1 Week		Sanofi	
	Methotrexate			S				Not Reported	
	Sulfasalazine			S				Not Reported	
	Azathioprine Sodium			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680987	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099339		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Intolerance; Hand Deformity; Headache; Pain In Extremity; Peripheral Swelling;	Hydroxychloroquine Sulfate			S				Sanofi	
	Arava			S				Sanofi	
	Methotrexate			S		25 Mg, Qd		Not Reported	
	Hydroxychloroquine			S				Sanofi	
	Sulfasalazine			S				Not Reported	

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Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680988	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099287		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatic Disorder	Hydroxychloroquine Sulfate			S	Oral	50 Mg		Sanofi
	Sulfasalazine			S				Not Reported
	Arava			S	Subcutaneous			Sanofi
	Humira			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Cymbalta			C				Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Hydromorphone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680991	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099390			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Mood Altered	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported

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

	Simponi		S	Subcutaneous				Not Reported	
	Actemra		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680992	EXPEDITED (15-DAY)		HO	CA-SA-2020SA099085			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Dehydration; Drug Ineffective	Plaquenil			S				Sanofi	
	Methotrexate			S				Not Reported	
	Prednisone			S				Not Reported	
	Leflunomide			S		Unk		Sanofi	
	Azathioprine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680993	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099325			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown			Sanofi	
	Arava			S	Unknown	Unk		Sanofi	
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680994	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100515			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi	

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Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Sulfasalazine	S	Oral	2000 Mg	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Sanofi
	Acetaminophen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk Unk, Qw	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681009	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099110			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gout; Pneumonia	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Metformin Hydrochloride			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Sanofi
	Colchicine			S	Unknown			Not Reported
	Sitagliptin			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681011	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099608		49 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681360	EXPEDITED (15-DAY)		OT	NVSC2020CA102910			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Psoriatic Arthropathy	Cosentyx			S	Unknown	Unk		Novartis
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

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	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelera	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681818	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019820		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Ertapenem			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo	
	Piperacillin+Tazobactam 4/0.5g Powderfor solutionfor infusion			S	Intravenous (not otherwise specified)	Unk Unk, Once A Day		Aurobindo	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681820	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-019814		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Hydroxychloroquine			S	Oral	200 Milligram, Two Times A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681821	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019810		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17685294	DIRECT					52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dyspnoea; Heart Rate Irregular; Palpitations; Pneumonia	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	11595241	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1641772		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Condition Aggravated; Cystitis; Cystitis; Diarrhoea; Dizziness; Nausea; Pain; Pneumonia; Sensitivity To Weather Change; Swelling; Urinary Tract Infection	Esbriet			S	Oral			Not Reported	
	Esbriet			S	Oral			Not Reported	
	Esbriet			S	Unknown			Not Reported	
	Esbriet			S	Unknown	Dose Increased To 9 Capsules A Day, Every 1 Day		Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Xeljanz			S	Oral			Not Reported	

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Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Cephalexin [Cefalexin]	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Therapy Duration: 2 Years			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	15292197	EXPEDITED (15-DAY)	CA, DE, DS, OT		DE-AUROBINDO-AUR-APL-2018-041851			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe Tablets			S	Transplacental	From Gestational Week 0-14		Aurobindo	
	Pantoprazole			S	Transplacental	40 Milligram, Once A Day		Aurobindo	
	Acetylsalicylic Acid			S	Transplacental	100 Milligram, Once A Day		Not Reported	
	Ramipril			S	Transplacental	20 Milligram, Once A Day, From Gestational Week 0-113+6		Aurobindo	
	Simvastatin Film-Coated Tablet			S	Transplacental	From Gestational Week 0-14		Aurobindo	
	Aspirin			S	Transplacental	100 Milligram, Once A Day (From Gestational Week 0-14)		Not Reported	
	Aspirin			S				Not Reported	
	Aliskiren			S	Transplacental	300 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S	Transplacental	400 Milligram, Once A Day		Not Reported	
	Metamizole			S	Transplacental	From Gestational Week 0-14		Not Reported	
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported	
	Prednisolone			S	Transplacental	10 Milligram, Two Times A Day From Gestational Week 0-14		Not Reported	
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported	

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Salbutamol	S	Transplacental	Unk, Once A Day, From Gestational Week 0-14	Not Reported
Tacrolimus	S	Transplacental	6 Milligram, Once A Day	Not Reported
Tacrolimus	S			Not Reported
Torsemide	S	Transplacental	100 Milligram, Once A Day	Not Reported
Heparin	S	Transplacental	Unk	Not Reported
Clexane	S	Transplacental	From Gestational Week 0-14	Not Reported
Clexane	S	Transplacental	200 Milligram, Once A Day	Not Reported
Dalteparin	S	Transplacental	Unk	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682209	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-019426		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported

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	Paracetamol	C	Unknown	Unk		Not Reported
	Xarelto	C	Oral	Unk		Not Reported
	Diffu K	C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682256	EXPEDITED (15-DAY)		HO, OT	SE-AUROBINDO-AUR-APL-2020-018861		16 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fatigue;	Sertraline			S	Oral	750 Milligram		Aurobindo	
Intentional Overdose;	Prednisolone			S	Oral	10-15st.		Not Reported	
Intentional Self-Injury;	Plaquenil			S	Oral	10-15 St.		Not Reported	
Somnolence; Tachycardia									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682362	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003499			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Promyelocytic	Hydroxychloroquine			S	Unknown	Unk		Concordia	
Leukaemia; Neutropenia;	Methotrexate			S	Unknown	Unk		Not Reported	
Off Label Use;	Methylprednisolone			S	Unknown	Unk		Not Reported	
Thrombocytopenia	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682415	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13043			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
Antibody Test Positive;	Infliximab			S	Unknown			Not Reported	
Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein	Adalimumab			S	Subcutaneous	Unknown		Not Reported	

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Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen	S	Unknown Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223766			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Actavis
	Azathioprine			S	Oral			Not Reported
	Bisoprolol Fumarate			S	Unknown			Duramed
	Methotrexate			S	Unknown			Barr
	Pantoprazole			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Zopiclone			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

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

	Nifedipine	S	Unknown					Not Reported	
	Rivotril	S	Unknown					Not Reported	
	Zantac	S	Unknown					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682516	EXPEDITED (15-DAY)		DE, OT	BR-ADVANSZ PHARMA-202004002764			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682522	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223780			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Morphine Hydrochloride			S	Unknown			Not Reported	
	Bisoprolol			S	Unknown			Duramed	
	Methotrexate			S	Unknown			Barr	
	Pantoprazole			S	Unknown			Actavis	
	Prednisone			S	Unknown			Actavis	
	Zopiclone			S	Unknown			Not Reported	
	Cefixime			S	Unknown			Not Reported	
	Imuran			S	Oral			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Nifedipine			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Rivotril			S	Unknown			Not Reported	
	Zantac			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682567	EXPEDITED (15-DAY)		OT	RO-ADVANSZ PHARMA-202004003329			Unknown	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	1 Dosage Form, Qd		Concordia	
	Euthyrox			S	Unknown	125 Ug, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682578	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004002839			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Infection; Joint Injury	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	13165412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-005507		62 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram		Not Reported	
	Methotrexate			S	Unknown	15 Milligram		Not Reported	
	Methotrexate			S	Unknown	150 Milligram		Not Reported	
	Methotrexate Sodium			S	Unknown	15 Milligram		Not Reported	
	Xeljanz			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Product Effect Incomplete;
Treatment Failure; White
Blood Cell Count
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	13852964	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-070668		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Osteoporosis; Pain; Rash; Synovitis	Orencia			S	Unknown	Unk Unk, Qmo		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Apo-Naproxen			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Methotrexate [Methotrexate Sodium]			S	Subcutaneous	25 Milligram, Qwk		Not Reported	
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported	
	Sulfasalazine			S	Unknown	2 Gram		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, Bid		Not Reported	
	Rituxan			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Oral	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Bid		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Unk		Not Reported	
	Naproxen			C	Unknown	Unk		Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Arava			C	Oral	20 Milligram, Qd		Not Reported	

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

Risedronate C Oral 35 Milligram, Qwk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	15751693	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-044237		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Fracture; Anti-Cyclic Citrullinated Peptide	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
Antibody Positive;	Actemra			S	Unknown	Unk		Not Reported
Arthralgia; Asthenia; Bone Density Abnormal;	Enbrel			S	Subcutaneous	Unk		Not Reported
Decreased Appetite;	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
Disability; Drug Ineffective;	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
Drug Intolerance;	Prednisone			S	Unknown	50 Milligram		Not Reported
Headache;	Prednisone			S	Oral	3 Mg, Qd		Not Reported
Hypercholesterolaemia;	Prednisone			S	Oral	25 Milligram, Qd		Not Reported
Infection; Joint Stiffness;	Prednisone			S	Oral	50 Milligram, Qwk		Not Reported
Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis;	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
Nausea; Neck Deformity; Neck Mass; Pain;	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
Rheumatoid Arthritis;	Sulfasalazine			S	Oral	1 Gram, Bid		Not Reported
Rheumatoid Factor Positive; Stress;	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Apo-Prednisone			S	Unknown	50 Milligram		Not Reported
Treatment Failure;	Apo-Prednisone			S	Unknown	25 Milligram, Qd		Not Reported
Unevaluable Event;	Apo-Prednisone			S	Oral	3 Milligram, Qd		Not Reported
Vomiting	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Indocid [Indometacin]			S	Unknown	Unk		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	400 Milligram, Qd		Not Reported
	Gold (198 Au) Colloidal			S	Unknown	Unk		Not Reported

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

Methotrexate Sodium	S	Oral	25 Milligram, Qwk	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Arava	S	Unknown	20 Milligram, Qd	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Hydroxychloroquine [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Cymbalta	C	Unknown	30 Milligram, Qd	Not Reported
Folic Acid Aventis	C	Oral	Unk Unk, Qwk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17563464	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022239		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody	Orencia			S	Intravenous (not otherwise specified)	250 Milligram		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Q2wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, Qwk		Not Reported
	Anakinra			S	Unknown	50 Milligram		Not Reported
	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported

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

Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthrititis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Enbrel	S	Unknown	1.5 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	50 Milligram	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram/Sq. Meter	Not Reported
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Triamcinolone	S	Other	Unk	Not Reported
	Intravenous Immunoglobulin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Triamcinolone Hexacetonide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682710	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1223867		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Indometacin			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	25 Milligram Daily;		Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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

Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Cymbalta	C	Oral	30 Milligram Daily;	Not Reported
Folic Acid	C	Oral		Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682746	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-018681			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematous; Treatment Failure; Wound	Alendronic Acid			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Methotrexate			S	Intra-arterial	25 Milligram, Once A Day		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

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

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682764	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-12491			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Blood Iron Abnormal; Condition Aggravated; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Laryngeal Disorder; Nausea; Off Label Use; Pain; Pruritus; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Azathioprine			S	Unknown	Unknown		Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Arava			S	Oral			Not Reported	
	Azathioprine			S	Unknown	Unknown		Not Reported	
	Azathioprine			S	Unknown	Unknown		Not Reported	
	Certolizumab Pegol			S	Unknown			Not Reported	
	Certolizumab Pegol			S	Unknown			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Ciclosporin			S	Oral	Unknown		Not Reported	
	Cimzia			S	Subcutaneous	Solution, Single Use Pre-Filled Syringe		Not Reported	

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

Enbrel	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Gold	S	Unknown	Unknown	Not Reported
Humira	S	Unknown		Not Reported
Humira	S	Subcutaneous	Solution	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Lyrica	S	Unknown	Unknown	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Unknown	Not Reported
Pregabalin	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Simponi	S	Subcutaneous	Unknown. Solution	Not Reported
Sodium Aurothiomalate	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Unknown	Not Reported
Folic Acid	C	Unknown		Not Reported

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

Piroxicam	C	Unknown	Unknown	Not Reported
Prednisone	C	Oral	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Unknown	Not Reported
Xeljanz	C	Oral		Not Reported
Leflunomide	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682792	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2020-019423		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg D1 Then 250 Mg Per Day		Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682818	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-030938			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Arthralgia;	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Arthritis; Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Fibromyalgia;	Actemra			S	Unknown	Unk		Not Reported	
Herpes Zoster; Infection;	Arava			S	Unknown	20 Milligram, Qd		Not Reported	
Joint Swelling;	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported	
Leukopenia; Liver Function Test Abnormal;	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Oral Pain; Peripheral Swelling; Pneumonia Viral;	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported	
Product Use Issue; Soft Tissue Disorder; Synovitis;	Methotrexate			S	Unknown	25 Milligram, Q4wk		Not Reported	
Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)	300 Milligram		Not Reported	
	Sodium Aurothiomalate			S	Intramuscular	Unk		Not Reported	
	Xeljanz			S	Unknown	Unk		Not Reported	
	Acetaminophen			C	Unknown	Unk		Not Reported	

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

Anakinra	C	Unknown	Unk	Not Reported
Ativan	C	Unknown	Unk	Not Reported
Benadryl [Acrivastine]	C	Unknown	Unk	Not Reported
Codeine	C	Unknown	Unk	Not Reported
Darifenacin	C	Unknown	Unk	Not Reported
Desoximetasone	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Dilaudid	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Kadian	C	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Unk	Not Reported
Lasix [Furosemide]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk	Not Reported
Omnaris	C	Unknown	Unk	Not Reported
Orphenadrine Citrate	C	Unknown	Unk	Not Reported
Oxyneo	C	Unknown	Unk	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Restasis	C	Unknown	Unk	Not Reported
Rituximab	C	Intravenous drip	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Trimethoprim	C	Unknown	Unk	Not Reported
Urispas	C	Unknown	Unk	Not Reported
Vagifem	C	Vaginal	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682829	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-031379			Male	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Orencia			S	Endocervical			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported	
	Arava			S	Unknown	25 Milligram, Qwk		Not Reported	
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown	25 Milligram, Qwk		Not Reported	
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682830	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031430		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rosuvastatin			S	Unknown			Not Reported	
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682831	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-031383			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematousus	Orencia			S	Subcutaneous			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Folic Acid			S	Unknown	5 Milligram		Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported	
	Enbrel			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	12289723	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-LUPIN PHARMACEUTICALS INC.-2016-01536			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure	Hydroxychloroquine			S	Transplacental	Unk (From Gestational Week 0-14)		Lupin	

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

During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril	S	Transplacental	20 Milligram, Qd (From Gestational Week 0-113+6)	Lupin
	Simvastatin Tablets	S	Transplacental	Unk (From Gestational Week 0-14)	Lupin
	Ezetimibe	S	Transplacental	Unk	Not Reported
	Ezetimibe	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Pantoprazole	S	Transplacental	40 Milligram, Qd (0-13.6 Gestational Week)	Not Reported
	Acetylsalicylic Acid	S	Transplacental	100 Milligram, Qd (From Gestational Week 0-14)	Not Reported
	Xarelto	S	Transplacental	Unk (From Gestational Week 0-5)	Not Reported
	Clexane	S	Transplacental	200 Milligram, Qd	Not Reported
	Tacrolimus	S	Transplacental	6 Milligram, Qd (From Gestational Week 0-14)	Not Reported
	Torasemide	S	Transplacental	100 Milligram, Qd	Not Reported
	Salbutamol	S	Transplacental	Unk Unk, Qd ((From Gestational Week 0-14))	Not Reported
	Enoxaparin Sodium	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Nicotine	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Prednisolone	S	Transplacental	10 Milligram, Bid (From Gestational Week 0-14)	Not Reported
	Novaminsulfon	S	Transplacental	Unk (Trimester: First; Probably Only In Hospital In Week 5)	Not Reported
	Dalteparin Sodium	S	Transplacental	Unk	Not Reported
	Metamizole	S	Transplacental	Unk (From Gestational Week 0-14)	Not Reported
	Rituximab	S	Transplacental	Unk (Trimester: Preconceptional)	Not Reported

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

Heparin Lmw	S	Transplacental	Unk	Not Reported
Aliskiren	S	Transplacental	300 Milligram, Qd (0-4.6 Gestational Week)	Not Reported
Heparin	C	Transplacental	Unk	Not Reported
Cyclophosphamide	C	Transplacental	Unk (3000 [Mg Cumulative]; Preconceptional)	Not Reported
Mifegyne	C	Transplacental	Unk (13.6 Gestational Week)	Not Reported
Cytotec	C	Transplacental	Unk (13.6 Gestational Week)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	12769848	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076833			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	500 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulphate			S	Oral	Unk		Not Reported
	Hydroxychloroquine Sulphate			S	Unknown	Unk		Not Reported

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

Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	Unk, Bid	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Gold	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Cannabis Sativa	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported

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

Methotrexate Sodium	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk, Q12h	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown		Not Reported
Oxyquinoline Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Rituximab;Urelumab	C	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	14217957	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP021473			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	Unk		Apotex

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

Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Alendronate	S	Unknown	70 Mg, Q.I.W	Apotex
Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug	Leflunomide	S	Unknown	Unk	Apotex
Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, B.I.Wk. (Duration:944)	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Unknown	12 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Unknown	10 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.I.W	Not Reported
	Methotrexate Sodium	S	Unknown	12.5 Mg, Q.I.W	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk (Duration: 366)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	680 Mg, One Every 4 Weeks	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
	Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	10 Mg, Qd	Not Reported
	Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	15634974	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105454			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Ankylosing Spondylitis; Condition Aggravated;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying;	Actemra			S	Unknown	Unk		Not Reported
Influenza; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown	2.5 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported
	Infliximab			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	15635082	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-105542		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cardiac Disorder; Deep Vein	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported

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

Thrombosis; Diverticulitis;	Anakinra	S	Unknown	Unk	Not Reported
Drug Hypersensitivity;	Anakinra	S	Unknown		Not Reported
Drug Ineffective; Drug	Arava	S	Unknown	Unk	Not Reported
Intolerance; Feeling	Arava	S	Unknown		Not Reported
Abnormal; Haemoglobin	Enbrel	S	Subcutaneous	Unk	Not Reported
Decreased; Herpes	Enbrel	S	Unknown		Not Reported
Zoster; Intentional Product	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Use Issue; Interstitial Lung	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Disease; Joint Swelling;	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Myocardial Infarction;	Ilaris	S	Subcutaneous	Unk	Not Reported
Pain; Photosensitivity	Ilaris	S	Unknown		Not Reported
Reaction; Pulmonary	Methotrexate	S	Intra-arterial	Unk	Not Reported
Embolism; Pulmonary	Methotrexate	S	Unknown		Not Reported
Thrombosis; Red Blood	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Cell Sedimentation Rate	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
Increased; Renal Failure;	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sepsis; Stomatitis;	Remicade	S	Unknown		Not Reported
Terminal State;	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Thrombosis; Urticaria	Rituxan	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported

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

Oxycodone	S	Unknown	10 Milligram	Not Reported
Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Rituximab	C	Unknown	Unk	Not Reported
Urelumab	C	Unknown	Unk	Not Reported
Lyrica	C	Oral		Not Reported
Prednisone	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Xeljanz	S	Oral	Unk, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	15840631	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001079			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	16045300	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020351		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia;	Methotrexate			S	Unknown			Barr	
Bone Density Decreased;	Leflunomide			S	Unknown			Barr	
Cataract; Diarrhoea;	Leflunomide			S	Unknown			Barr	
Dizziness; Drug	Actemra			S	Unknown			Not Reported	
Ineffective; Drug	Actemra			S	Unknown			Not Reported	
Ineffective; Drug	Mobicox			S	Unknown			Not Reported	
Ineffective; Drug	Gold			S	Unknown			Not Reported	
Intolerance; Drug	Humira			S	Subcutaneous			Not Reported	
Intolerance; Dry Eye;	Hydroxychloroquine			S	Unknown			Not Reported	
Fatigue; Feeling	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Abnormal; Fibromyalgia;	Orencia			S	Unknown			Not Reported	
Hand Deformity; Joint	Depo-Medrol			C	Other	80 Milligram Daily;		Not Reported	
Range Of Motion	Depo-Medrol			C	Other			Not Reported	
Decreased; Joint Swelling;	Diclofenac			C	Unknown			Not Reported	
Malaise; Mobility	Pantoprazole Magnesium			C	Unknown			Not Reported	
Decreased; Muscular	Plaquenil			C	Unknown			Not Reported	
Weakness;	Prednisone			C	Unknown			Not Reported	
Musculoskeletal Pain;	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	
Musculoskeletal Stiffness;									
Myalgia; Pain; Pain In									
Extremity; Pain In									
Extremity; Peripheral									
Swelling; Pulmonary									
Toxicity; Rash Maculo-									
Papular; Rash Pruritic;									
Rheumatoid Arthritis;									
Rheumatoid Lung;									
Synovial Cyst; Synovitis;									
Tenosynovitis; Viral Upper									
Respiratory Tract Infection									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	16079806	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 05468			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported	
	Actemra			S	Unknown	Unknown		Not Reported	
	Enbrel			S	Unknown	Unknown		Not Reported	
	Simponi			S	Subcutaneous	Unknown, Solution		Not Reported	
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported	
	Leflunomide			S	Oral	Unknown		Not Reported	
	Methotrexate			S	Unknown	Unknown		Not Reported	
	Sulfasalazine			S	Unknown	Unknown		Not Reported	
	Aspirin			C	Unknown	Unknown		Not Reported	
	Clopidogrel Bisulfate			C	Oral	Unknown		Not Reported	
	Ezetrol			C	Oral	Unknown		Not Reported	
	Niaspan			C	Unknown	Unknown, Extended Release Tablet		Not Reported	
	Nitroglycerin			C	Transdermal	Unknown		Not Reported	
	Rosuvastatin Calcium			C	Oral	Unknown		Not Reported	
	Tylenol			C	Oral	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	16563279	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019- 17758		3 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Arthropathy; Body Height	Infliximab			S	Intravenous (not			Not Reported	

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Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Product Use In Unapproved Indication; Product Use Issue; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra	S	otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Unknown	Unknown, Other Route	Not Reported
	Naproxen	S	Unknown	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Triamcinolone Hexacetonide	C	Unknown	Unknown	Not Reported

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20-Apr-2020	16936907	EXPEDITED (15-DAY)		CA, OT	DE-BAUSCH-BL-2019-057945		1 DAY	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Hand Malformation; Developmental Hip Dysplasia; Foetal Exposure During Pregnancy; Small For Dates Baby	Prednisolone			S	Transplacental	Maternal Dose: 5mg, Qd (One In One Day)		Not Reported
	Quensyl			S	Transplacental	Maternal Dose: 200 (Mg/D)/Varying Dosage Between 150 And 200 Mg Daily		Not Reported
	Mono-Embolex			C	Transplacental	Maternal Dose: 3000 (Ie/D)		Not Reported
	L-Thyroxin Jod Beta			C	Transplacental	Maternal Dose: 37.5 (Microg/D) / 75(Microg/D)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17528005	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA067701		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Novartis
	Diclofenac			S	Oral	2 Df, Qd		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral	75 Mg, Bid		Novartis
	Diclofenac			S	Oral			Novartis
	Diclofenac			S	Oral	Unk, Qd		Novartis
	Diclofenac			S	Oral	Unk		Novartis
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported

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Voltaren Sr	S	Oral	2 Df, Qd (75 Mg)	Not Reported
Voltaren Sr	S	Oral	Unk	Not Reported
Diclofenac Potassium	S	Oral		Novartis
Cambia	S	Oral	Unk, Qd	Not Reported
Cambia	S	Oral	Unk	Not Reported
Cambia	S	Unknown	75 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)	Not Reported
Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	1 Df, Qd	Not Reported
Synthyroid	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Gold	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17584672	EXPEDITED (15-DAY)		OT	NVSC2020US083168			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease; Gastrointestinal Pain; Joint Swelling	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	Unk		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17597328	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009074		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling;	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex	
	Hydroxychloroquine			S	Oral	400 Mg, Unk		Apotex	
	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Apo-Hydroxyquine			S	Unknown	Unk		Apotex	

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Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Apotex
	Leflunomide	S	Unknown	10 Mg, Unk	Apotex
	Leflunomide	S	Oral	20 Mg, Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Gold	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	15 Mg, Qd	Not Reported
	Methotrexate	S	Endocervical	25 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	50 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Simponi	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17652112	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1218243		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ascites; Atrioventricular Block First Degree; Cardiac Failure; Cardiomyopathy; Diastolic Dysfunction; Fluid Overload; Left Ventricular	Hydroxychloroquine			S	Unknown	Initial Dosage Not Stated; Tit		Teva	
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; Rated To 200mg Twice Daily In The First Year		Teva	

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Dysfunction; Right	Prednisone	C	Unknown	Not Reported
Ventricular Dysfunction; Toxicity To Various Agents	Rituximab	C	Other	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17675973	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA097041			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Arava			S	Oral	10 Mg, Qd		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Intramuscular	25 Mg, Qw		Not Reported
	Leflunomide			S	Oral	10 Mg, Qd		Sanofi
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Asa			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Gliclazide]			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported

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20-Apr-2020	17682990	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 12849		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown	Unknown		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	
	Methotrexate			S	Unknown	Unknown		Not Reported	
	Orencia			S	Unknown	Unknown		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Intravenous (not otherwise specified)	Unknown		Not Reported	
	Xeljanz			S	Unknown	Unknown		Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Esomeprazole Sodium			C	Unknown	Unknown		Not Reported	
	Lumigan Rc			C	Ophthalmic	Unknown		Not Reported	
	Lyrica			C	Unknown			Not Reported	
	Sulfasalazin			C	Unknown			Not Reported	
	Suphedrine [Pseudoephedrine Hydrochloride]			C	Unknown			Not Reported	
	Trazodone			C	Unknown			Not Reported	
	Valsartan			C	Unknown	Unknown		Not Reported	
	Wellbutrin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683235	EXPEDITED (15-DAY)		HO	FR-ADVANSZ PHARMA- 202004003379			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Oxygen Consumption Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia	
	Nicardipine			C		Unk		Not Reported	
	Lovenox			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683260	EXPEDITED (15-DAY)		HO	SE-TEVA-2020-SE-1224953		16 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15st.		Actavis	
	Sertraline			S	Oral	750 Mg		Not Reported	
	Plaquenil			S	Oral	10-15 St.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584741			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Lymphoma	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Desoximetasone			C	Unknown			Not Reported	
	Diclofenac			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683398	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584183			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituxan			S	Intravenous drip			Not Reported	
	Cimzia			S	Subcutaneous	Single Use		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585127		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Ergocalciferol			C				Not Reported	
	Folinic Acid			C				Not Reported	
	Prednisone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683443	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-031020		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb	



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Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label Use; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Actemra	S	Unknown	360 Milligram	Not Reported
	Actemra	S	Unknown	360 Milligram	Not Reported
	Actemra	S	Unknown	360 Milligram, Qmo	Not Reported
	Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Enbrel	S	Unknown	25 Milligram	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15.0 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported

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Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram, Q12h	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683489	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585203		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Methotrexate			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683494	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1805			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Constipation; Drug	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

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Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683880	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA101018		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S		15 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	400 Mg, Solution		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral	5 Mg		Not Reported
	Prednisone			C				Not Reported
	Aleve			C				Not Reported
	Arava			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683881	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100510			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Hydroxychloroquine Sulfate	S	Unknown		Sanofi
	Arava	S	Unknown	200 Mg, Qd	Sanofi
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	S	Unknown	5 Mg, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Acetaminophen	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100531		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobility; Malaise	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Celecoxib			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Naproxen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683915	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099405			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling;	Hydroxychloroquine Sulfate			S		Unk, Bid		Sanofi
	Actemra			S				Not Reported
	Arava			S		20 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported

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Pneumonia Viral; Soft Tissue Swelling; Synovitis	Sodium Aurothiomalate	S						Not Reported
	Xeljanz	S						Not Reported
	Acetaminophen	C						Not Reported
	Ativan	C						Not Reported
	Anakinra	C			Unk			Not Reported
	Codeine	C						Not Reported
	Darifenacin	C						Not Reported
	Desoximetason	C						Not Reported
	Dilaudid	C						Not Reported
	Diphenhydramine	C						Not Reported
	Hydromorphone	C						Not Reported
	Kadian	C						Not Reported
	Kenalog [Triamcinolone Acetonide]	C	Intra-articular		Suspension Intra-Articular			Not Reported
	Oxyneo	C						Not Reported
	Synthroid	C						Not Reported
	Urispas	C						Not Reported
	Trimethoprim	C						Not Reported
	Vagifem	C	Vaginal					Not Reported
	Pantoprazole Sodium Anhydrous	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683917	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099622			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Leflunomide			C		20 Mg, Qd		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C		3 G, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100527		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi	
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi	
	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Methotrexate			C	Subcutaneous	17.5 Mg, Qw		Not Reported	
	Methotrexate			C	Subcutaneous	15 Mg, Qw		Not Reported	
	Sulfasalazine			C	Oral	1 G, Qd		Not Reported	
	Xeljanz			C		5 Mg, Qd (2 Every 1 Days)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683921	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100715			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Hydroxychloroquine Sulfate			S	Oral			Sanofi	
	Leflunomide			S	Oral			Sanofi	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Actemra			S				Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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Xeljanz			C	Oral	5 Mg, Q12h			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683933	EXPEDITED (15-DAY)	OT		CA-SA-2020SA100719			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction;	Plaquenil			S				Sanofi	
Colectomy; Diarrhoea;	Arava			S				Sanofi	
Drug Hypersensitivity;	Codeine			S				Not Reported	
Drug Hypersensitivity;	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported	
Drug Hypersensitivity;	Prednisone			S				Not Reported	
Speech Disorder	Sulfasalazine			S				Not Reported	
Developmental; Treatment	Enbrel			S				Not Reported	
Failure; Treatment Failure	Imuran [Azathioprine]			S				Not Reported	
	Simponi			S	Subcutaneous	Solution		Not Reported	
	Humira			S	Subcutaneous	Solution		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683934	EXPEDITED (15-DAY)	OT		CA-SA-2020SA100245		48 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Plaquenil			S		Unk		Sanofi	
Musculoskeletal Pain;	Methotrexate			S		Unk		Not Reported	
Pain In Extremity;	Arava			S		Unk		Sanofi	
Pancreatic Carcinoma;	Sulfasalazine			S		Unk		Not Reported	
Peripheral Swelling;	Actemra			S		Unk		Not Reported	
Rheumatoid Arthritis;	Humira			S	Subcutaneous	Unk		Not Reported	
Splenectomy; Swelling;	Simponi			S	Subcutaneous	Unk		Not Reported	
Therapeutic Product Effect									
Decreased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683935	EXPEDITED (15-DAY)	OT		CA-SA-2020SA100641		59 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Leukopenia; Neutropenia	Hydroxychloroquine			S	Oral	20 Mg, Qd		Sanofi	
	Leflunomide			S				Sanofi	
	Methotrexate			S				Not Reported	
	Sulfasalazine			S				Not Reported	
	Azathioprine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA099415			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia	Hydroxychloroquine Sulfate			S		400 Mg, Qd (1 Every 1 Day)		Sanofi	
	Leflunomide			S		Sanofi			
	Methotrexate			S		Not Reported			
	Rituximab			S		Not Reported			
	Orencia			S		Not Reported			
Enbrel			S	Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100724			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Plaquenil			S	Oral	100 Mg		Sanofi	
	Bisoprolol Salt Not Specified			S				Not Reported	
	Cefixime			S				Not Reported	
	Methotrexate			S				Not Reported	
	Morphine Hydrochloride			S				Not Reported	
	Nifedipine			S				Not Reported	
	Pantoprazole			S				Not Reported	
	Prednisone			S				Not Reported	
	Clonazepam			S				Not Reported	
	Zantac			S				Sanofi	
	Zopiclone			S				Not Reported	
	Imuran [Azathioprine]			S				Not Reported	

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

Infliximab	S	Intravenous (not otherwise specified)	5.0 Mg/Kg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683939	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100517			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Hydroxychloroquine Sulfate			S		40 Mg		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported
	Folic Acid			C	Unknown			Not Reported
Methotrexate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683954	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585160			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Ciclosporin			S				Not Reported
	Ciclosporin			S				Not Reported
	Imatinib			S	Unknown			Not Reported
	Imatinib			S				Not Reported

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

Imatinib	S		Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Imuran [Azathioprine]	S		Not Reported
Imuran [Azathioprine]	S		Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S		Not Reported
Prednisone	S		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Tacrolimus	S	Unknown	Not Reported
Tacrolimus	S		Not Reported
Tacrolimus	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684002	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224352			Female	CAN

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224903		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr	
	Naproxen			S	Unknown			Teva	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684130	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224385		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abnormal Loss Of Weight; Alopecia; Arthritis; Drug Ineffective; Hepatic Enzyme Abnormal; Myocardial Infarction; Rash	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Humira			S	Subcutaneous	80 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Aspirin [Acetylsalicylic Acid]			C				Not Reported	
	Clopidogrel Bisulfate			C				Not Reported	
	Metoprolol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Ramipril			C				Not Reported	
	Rosuvastatin			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224905		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Oral	20 Milligram Daily;		Barr	
	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Methotrexate			C	Subcutaneous			Not Reported	
	Methotrexate			C	Subcutaneous			Not Reported	
	Sulfasalazine			C	Oral	1 Gram Daily;		Not Reported	
	Xeljanz			C	Unknown	10 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224454			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Varenicline Tartrate			S	Oral	1 Milligram Daily;		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Valtrex	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684161	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584882			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684208	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100329			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Arthralgia; Drug	Hydroxychloroquine	S		200 Mg, Qd	Sanofi
Hypersensitivity; Drug	Arava	S	Oral	20 Mg, Qd	Sanofi
Ineffective; Knee	Actemra	S		200 Mg, Qm	Not Reported
Arthroplasty; Medical	Enbrel	S			Not Reported
Device Implantation	Folic Acid	S		1 Mg, Qd	Not Reported
	Humira	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684209	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA100717			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
Drug Ineffective; Drug	Sulfasalazine			S				Not Reported
Intolerance; Fatigue; Gait	Leflunomide			S		20 Mg, Qd		Sanofi
Disturbance; Loss Of	Acetaminophen			S				Not Reported
Personal Independence In	Actemra			S				Not Reported
Daily Activities; Malaise;	Enbrel			S		50 Mg, Qw		Not Reported
Rheumatoid Arthritis;	Humira			S	Subcutaneous			Not Reported
Somnolence; Visual	Cimzia			S	Subcutaneous	Unk		Not Reported
Impairment	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C		1 Df, Qw		Not Reported
	Meloxicam			C				Not Reported
	Synthroid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684211	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098991			Female	CAN

FDA Adverse Event Reporting System

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Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Herpes Zoster; Ill-Defined Disorder; Malaise; Pain; Rheumatoid Factor Increased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S				Sanofi
	Diclofenac			S				Not Reported
	Methotrexate			S		20 Mg, Qw		Not Reported
	Arthrotec			C				Not Reported
	Desoximetasone			C				Not Reported
	Ibuprofen			C				Not Reported
	Naproxen			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Oral			Not Reported
	Prednisone			C	Oral	Unk Unk, Qd		Not Reported
	Sulfasalazine			C				Not Reported
	Synthroid			C		Unk Unk, Qd		Not Reported
	Tramadol			C	Oral	Unk Unk, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684214	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100514			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Intestinal Perforation	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684329	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224395			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Amenorrhoea; Anxiety;	Leflunomide	S	Oral	Barr
Burning Sensation; Drug	Leflunomide	S	Oral	Barr
Ineffective;	Leflunomide	S	Oral	Barr
Hypoaesthesia; Infection;	Leflunomide	S	Oral	Barr
Juvenile Idiopathic	Methotrexate	S	Unknown	Barr
Arthritis; Nausea;	Plaquenil	S	Unknown	Not Reported
Neuropathy Peripheral	Sulfasalazine	S	Unknown	Not Reported
	Celexa [Celecoxib]	C	Oral	Not Reported
	Cholecalciferol	C	Oral	Not Reported
	Ethinyl Estradiol/Norgestimate	C	Oral	Not Reported
1 Dosage Forms Daily;				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684330	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223969			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Leflunomide			S	Unknown			Barr
Drug Ineffective; Drug	Methotrexate			S	Unknown			Barr
Intolerance; Dyspepsia;	Actemra			S	Unknown			Not Reported
Joint Swelling; Therapy	Arava			S	Unknown			Not Reported
Partial Responder	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684454	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223977		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug	Leflunomide			S	Unknown			Barr
Intolerance; Fatigue;	Apo-Leflunomide			S	Unknown			Not Reported
Inflammatory Marker	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported
Increased; Irritable Bowel	Syringe							
Syndrome; Loss Of								

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

Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain In Extremity; Peripheral Swelling; Stress	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Dequalinium Chloride	C			Not Reported
	Mefenamic Acid	C	Unknown		Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	10 Milligram Daily;	Not Reported
	Prednisone	C	Oral	6 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684459	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224366		60 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

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

Methotrexate	S	Oral		Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Folic Acid	C	Oral	2.5 Milligram Daily;	Not Reported
Pantoprazole Magnesium	C	Unknown		Not Reported
Pantoprazole Magnesium	C	Oral	40 Milligram Daily;	Not Reported
Tenofovir Disoproxil	C	Unknown		Not Reported
Tenofovir Disoproxil	C	Oral		Not Reported
Zopiclone	C	Unknown	7.5 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224831		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Other	80 Milligram Daily; Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported

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

Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Pantoprazole Magnesium	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684526	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224892		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Naproxen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684531	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224908			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown		Barr
	Naproxen	S	Unknown		Teva
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684650	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224216			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Lyrica			S	Oral	300 Milligram Daily;		Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684658	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA100513			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi

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

Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Leflunomide	S			Sanofi
	Leflunomide	S	Unknown	Unk	Sanofi
	Leflunomide	S			Sanofi
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S			Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S			Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S			Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Humira	S			Not Reported
	Ilaris	S	Subcutaneous	Unk	Not Reported
	Ilaris	S			Not Reported
	Ilaris	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ilaris	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S			Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Remicade	S			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

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

Rituximab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S			Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA098969		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Hydroxychloroquine			S				Sanofi
Arthralgia; Asthenia; Blood	Hydroxychloroquine			S		Unk		Sanofi
Cholesterol Increased;	Allopurinol			S				Not Reported
Condition Aggravated;	Amitriptyline Hydrochloride			S				Not Reported
Disease Recurrence; Drug	Diclofenac Sodium			S	Topical	Solution Topical		Not Reported
Ineffective; Drug	Diclofenac Sodium			S		Unk		Not Reported
Interaction; Drug	Diclofenac Sodium			S		Unk		Not Reported
Intolerance;	Diclofenac Potassium			S				Not Reported
Gastroesophageal Reflux	Arava			S				Sanofi
Disease; Impaired Work	Arava			S		Unk		Sanofi
Ability; Malaise; Mobility	Arava			S		Unk, Apo-Leflunomide,		Sanofi
Decreased; Movement	Arava			S		Tablet		
Disorder; Muscle Spasms;	Naproxen			S				Not Reported
Off Label Use; Pain; Pain	Naproxen			S		Unk		Not Reported
In Jaw; Product	Naproxen			S		Unk, Apo-Naproxen		Not Reported
Complaint; Rash;	Prednisone			S		5 Mg, Apo-Prednisone		Not Reported
Rheumatoid Arthritis;	Prednisone			S		Unk		Not Reported
Swelling; Synovitis;	Prednisone			S		Unk, Winpred		Not Reported
Therapeutic Response	Celecoxib			S				Not Reported
Decreased; Wrist	Celecoxib			S		Unk		Not Reported
Deformity								

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

Celecoxib	S	Unk, Capsule	Not Reported
Celecoxib	S	Unk, Capsule	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Parenteral Unk	Not Reported
Methotrexate	S	Oral Unk	Not Reported
Methotrexate	S	Subcutaneous Unk	Not Reported
Methotrexate	S	Unk	Not Reported
Misoprostol	S		Not Reported
Pregabalin	S		Not Reported
Sulfasalazine	S		Not Reported
Amitriptyline	S		Not Reported
Amitriptyline With Perphenazine	S		Not Reported
Apo-Azathioprine	S		Not Reported
Azathioprine	S		Not Reported
Diclofenac Sodium And Misoprostol	S		Not Reported
Enbrel	S	Subcutaneous 50 Mg, Qw	Not Reported
Etanercept	S		Not Reported
Actemra	S		Not Reported
Humira	S	Subcutaneous 40 Mg	Not Reported
Lyrica	S		Not Reported
Nifedipine	S		Not Reported
Orencia	S	Subcutaneous 750 Mg, Qw	Not Reported
Rituximab	S	Intravenous (not otherwise specified) 2000 Mg	Not Reported
Xeljanz	S	Oral 5.0 Mg, Bid	Not Reported
Tofacitinib	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684872	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1223974		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein	Leflunomide			S	Unknown			Barr	

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

Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate	S	Unknown	Barr
	Methotrexate	S		Barr
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituximab	C	Unknown	Not Reported
	Urelumab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685014	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100424		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diverticulitis; Drug Ineffective; Injection Site	Hydroxychloroquine Sulfate			S				Sanofi	
Urticaria; Nausea; Rash; Urticaria	Leflunomide			S				Sanofi	
	Methotrexate			S	Oral	Unk		Not Reported	
	Methotrexate			S		Unk		Not Reported	
	Actemra			S				Not Reported	

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

Enbrel	S				Not Reported
Humira	S	Subcutaneous	Solution		Not Reported
Atenolol	C	Oral	50 Mg, Qd		Not Reported
Hydrochlorothiazide	C		25 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685016	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100528		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	14 Mg, Qd		Not Reported
	Arava			S	Unknown			Sanofi
	Celecoxib			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qm		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Furosemide			C	Unknown	Unk Unk, Qd		Not Reported
	Hydromorph Contin			C		18 Mg, Tid, Sustained Release		Not Reported
	Dilaudid			C	Unknown	4 Mg, Tid		Not Reported
	Lyrica			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685106	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224477			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Colitis	Leflunomide			S	Unknown			Barr

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

Ulcerative; Contraindicated Product Administered; Drug Ineffective; Effusion; Rheumatoid Factor Positive; Synovitis	Methotrexate	S	Unknown	Barr
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685109	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224361			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685110	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224214			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown	20 Mg		Barr	
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	

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

	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685113	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224210			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Sulfasalazine			S	Oral	3 Gram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224837		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled			S	Unknown			Not Reported	

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

Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Syringe Enbrel Hydroxychloroquine Sulfate Orencia Sulfasalazine Dorzolamide Hydrochloride/Timolol Maleate Ergocalciferol Estradiol Estrogel Furosemide Morphine Potassium Chloride Valsartan Xalatan Zingiber Officinale	S S S S C C C C C C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

1.8 Percent Daily;

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685278	EXPEDITED (15-DAY)		LT	CA-SAMSUNG BIOEPIS-SB-2020- 13385			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea;	Infliximab Actemra Actemra Anakinra Anakinra Apo-Naproxen Apo-Prednisone			S S S S S S S	Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Unknown Oral	Unknown		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Obesity; Off Label Use;	Enbrel	S	Subcutaneous		Not Reported
Product Use In	Humira	S	Subcutaneous	Unknown, Solution	Not Reported
Unapproved Indication;	Humira	S	Unknown	Unknown	Not Reported
Psoriasis; Quality Of Life	Hydroxychloroquine	S	Oral	Unknown	Not Reported
Decreased; Red Blood	Methotrexate	S	Subcutaneous		Not Reported
Cell Sedimentation Rate	Methotrexate	S	Unknown	Unknown	Not Reported
Increased; Septic Shock;	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Synovitis; Therapy Non-Responder; Vomiting;	Orencia	S			Not Reported
Wheelchair User	Sulfasalazine	S	Oral		Not Reported
	Triamcinolone	S	Intra-articular	Unknown	Not Reported
	Triamcinolone	S			Not Reported
	Folic Acid	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685511	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224221		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
Drug Ineffective; Elbow	Prednisone			S	Unknown			Actavis
Deformity; Headache;	Methotrexate			S	Unknown			Barr
Liver Function Test	Arava			S	Oral	20 Milligram Daily;		Not Reported
Increased; Rheumatoid	Enbrel			S	Subcutaneous			Not Reported
Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685527	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224426			Female	CAN

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685606	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13343		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Drug Ineffective For Unapproved Indication; Hypersensitivity; Incorrect Route Of Product Administration; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Subcutaneous	Unknown		Not Reported
	Methotrexate			S	Oral	Unknown		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Varicella-Zoster Immune Globulin			S	Subcutaneous	Liquid Intramuscular, Dose: Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685629	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223866		59 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685690	EXPEDITED (15-DAY)		OT	NVSC2020GB104678			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685725	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX008388		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non- Responder; Treatment Failure	Procytox (Cyclophosphamide) 2000mg/Vial	S	Unknown	Dosage Form: Not Specified	Baxter
	Mycophenolate Mofetil	S	Unknown	Dosage Form: Not Specified	Not Reported
	Mycophenolate Mofetil	S	Oral		Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Plaquenil	S	Unknown	Dosage Form: Tablet	Not Reported
	Rituxan	S	Unknown	Dosage Form: Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Cymbalta	C	Unknown	Dosage Form: Not Specified	Not Reported
	Domperidone	C	Unknown	Dosage Form: Tablet	Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685734	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224445			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Dizziness; Gastrointestinal Disorder; Headache; Hypotension; Joint Noise; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Psoriatic Arthropathy; Rheumatoid Arthritis; Sensitivity To Weather Change; Therapeutic Product Effect Decreased; Vaginal Haemorrhage; Vomiting; Weight Increased	Leflunomide			S	Oral	10 Milligram Daily;		Barr
	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leucovorin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported
	Calcium Citrate; Magnesium Citrate			C				Not Reported
	Citalopram Hydrobromide			C				Not Reported
	Clobetasol Propionate			C	Topical			Not Reported

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

	Naproxen	C	Oral					Not Reported
	Pantoprazole Magnesium	C						Not Reported
	Escitalopram Oxalate	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685735	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1224422		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Delirium;	Leflunomide			S	Unknown			Barr
Dislocation Of Vertebra;	Methotrexate			S	Unknown			Barr
Drug Hypersensitivity;	Cosentyx			S	Unknown			Not Reported
Drug Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Tolerance Decreased; Hip	Orencia			S	Unknown			Not Reported
Arthroplasty; Infection;	Rituximab			S	Intravenous drip			Not Reported
Knee Arthroplasty;	Simponi			S	Subcutaneous			Not Reported
Seronegative Arthritis;	Sulfasalazine			S	Unknown			Not Reported
Spinal Fusion Surgery;	Naproxen			C	Unknown			Not Reported
Therapeutic Product Effect								
Decreased; Type 2								
Diabetes Mellitus; Wound								
Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685779	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224435			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lung	Leflunomide			S	Unknown			Barr
Disorder; Respiratory	Methotrexate			S	Unknown			Barr
Disorder; Rheumatoid	Enbrel			S	Unknown			Not Reported
Arthritis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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

Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Desoximetason	C	Unknown	10 Milligram Daily; Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223872			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Urinary Tract Obstruction	Azathioprine Sodium			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685788	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223967			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Headache; Hepatotoxicity; Joint Swelling; Mucosal Ulceration; Nausea; Synovitis	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	4800 Milligram Daily;		Not Reported	
	Kevzara			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685791	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224383			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685813	EXPEDITED (15-DAY)		DE	ES-ASTRAZENECA- 2020SE51307		95 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Quetiapine			S	Oral			Zeneca	
	Hydroxychloroquine Sulphate			S	Oral			Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported	
	Kaletra			S	Oral	200/50 Mg, 2 Df Daily, 120 Tablets		Not Reported	
	Risperidone			S	Oral			Not Reported	
	Losartan			C	Oral			Not Reported	
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)			Not Reported	
	Lorazepam			C	Oral			Not Reported	

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Furosemide			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685815	EXPEDITED (15-DAY)		DS	CA-SAMSUNG BIOEPIS-SB-2020- 12772		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Drug Ineffective; Hand Deformity; Pain; Rheumatoid Arthritis; Swelling; Treatment Failure	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported	
	Humira			S	Subcutaneous	Unknown,		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unknown,		Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Sulfasalazine			S	Oral	Unknown		Not Reported	
	Acetaminophen/Oxycodone Hydrochloride			C	Unknown	Unknown		Not Reported	
	Celebrex			C	Oral	Unknown		Not Reported	
	Furosemide			C	Unknown	Unknown		Not Reported	
	Morphine			C	Unknown	Unknown		Not Reported	
	Oxycodone Terephthalate			C	Unknown	Unknown		Not Reported	
	Ramipril			C	Unknown	Unknown		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685895	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224217			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685905	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223975		51 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Cytology Abnormal; Drug Ineffective; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Unknown			Barr	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral	1 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown	1 Gram Daily;	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
Actemra	S	Unknown		Not Reported
Lyrica	C	Oral		Not Reported
Prednisone	C	Unknown	15 Milligram Daily;	Not Reported
Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685927	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224413			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Nausea; Neuropathy Peripheral	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Depo-Medrol			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685928	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223947			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism	Leflunomide			S	Unknown			Barr	
	Leflunomide			S				Barr	
	Methotrexate			S	Intra-arterial			Barr	
	Methotrexate			S				Barr	
	Actemra			S	Unknown			Not Reported	
	Actemra			S				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685929	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223955			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Symptom;	Leflunomide			S	Oral			Barr	
Alopecia; Arthralgia; Bone	Leflunomide			S	Oral			Barr	
Disorder; Cyst; Hand	Methotrexate			S	Unknown			Barr	
Fracture; Seronegative	Azathioprine			S	Unknown			Not Reported	
Arthritis; Urinary Tract	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
Obstruction	Sulfasalazine			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685981	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1224403			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Lung Disorder; Respiratory Disorder	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Remicade			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Desoximetason			C	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685990	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223963			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Drug Ineffective; Emphysema; Musculoskeletal Stiffness; Pain	Leflunomide			S	Oral	20 Milligram Daily;		Barr	
	Leflunomide			S	Oral	10 Milligram Daily;		Barr	
	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Oral			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686061	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1223940			Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Intra-arterial			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686242	EXPEDITED (15-DAY)		HO	CA-SAMSUNG BIOEPIS-SB-2020-13015		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Infliximab Infliximab Actemra Actemra Alendronate Codeine Hydroxychloroquine Sulfate Sulfasalazine Leflunomide Enbrel Humira Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Myochrysine Orencia Rituximab Xeljanz Prednisone Ciclosporin	S S S S S S S S S S S S S S S S S S S S S S S C C C	Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Subcutaneous Subcutaneous Subcutaneous Subcutaneous Subcutaneous Subcutaneous Oral Intramuscular Unknown Intravenous drip Unknown Unknown Unknown	Unknown Unknown	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686331	EXPEDITED (15-DAY)		OT	NVSC2020CA105008			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Aclasta			S	Intravenous (not otherwise specified)	Unk		Novartis
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plantago Afra			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported
	Lipitor			C	Unknown	10 Mg, Qd		Not Reported
	Methotrexate			C	Subcutaneous	22.5 Mg, Qw		Not Reported
	Folic Acid			C	Unknown	5 Mg		Not Reported
	Ergocalciferol			C	Unknown	2000 Iu, Qd		Not Reported
	Cannabis Sativa			C	Unknown	Unk Unk, Qd		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Asa			C	Unknown	81 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686344	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028- 3365681-00		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoea; Back Pain; Chest Pain; Cough; Diarrhoea; Drug Ineffective; Eye Irritation; Headache; Musculoskeletal Pain; Nasopharyngitis; Pleural Effusion; Pyrexia; Retinal Injury; Rhinorrhoea	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Methotrexate			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686390	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032357			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Qd		Not Reported	
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported	
	Xeljanz			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686431	EXPEDITED (15-DAY)		DS, OT	US-ADVANSZ PHARMA- 202004003537			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Vision Loss; Macular Degeneration; Maculopathy; Retinal Toxicity; Retinopathy; Vision Blurred	Hydroxychloroquine			S		800 Mg, Qd		Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686581	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2020-018504		21 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
	Ambisome			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	

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Tocilizumab S Intravenous (not otherwise specified) Unk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686584	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018508		63 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Ceftriaxone Dolquine			S S				Not Reported Not Reported
					400 Milligram, Once A Day			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17690121	DIRECT		HO				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	400mg Bid For 1 Day Then 200bid For 1 Day Bid Po X 1 Day(S)		Not Reported
	Azithromycin			S		500mg Qd X 1 250mg Daily For 3 Days Qd Po X 3 Day(S)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	12769487	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-015683			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Blood Glucose Increased; Blood Pressure Increased;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb

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C-Reactive Protein	Orencia	S	Unknown	200 Milligram	Bristol Myers Squibb
Abnormal; Condition	Tylenol	S	Unknown	As Needed	Not Reported
Aggravated; Drug	Enbrel	S	Unknown	50 Mg, Qwk(Loe)	Not Reported
Hypersensitivity; Drug	Enbrel	S	Unknown	40 Milligram	Not Reported
Ineffective; Drug	Enbrel	S	Unknown	50 Milligram, Qd	Not Reported
Intolerance; Fatigue;	Sulfasalazine	S	Oral	2000 Mg(Intolerance)	Not Reported
Femur Fracture; Gait	Sulfasalazine	S	Unknown	2 Gram	Not Reported
Disturbance; Gastric	Sulfasalazine	S	Oral	1000 Milligram, Qd	Not Reported
Disorder; Glycosylated	Actemra	S	Intravenous (not	800 Milligram	Not Reported
Haemoglobin Increased;			otherwise specified)		
Heart Rate Increased;	Actemra	S	Subcutaneous		Not Reported
Hepatic Enzyme	Arava	S	Oral	20 Mg, Qd	Not Reported
Increased; Hospitalisation;	Arava	S	Unknown	10 Milligram, Qd	Not Reported
Infection; Intentional	Cimzia	S	Subcutaneous		Not Reported
Product Misuse; Joint	Acetaminophen	S	Unknown	325 Milligram	Not Reported
Swelling; Loss Of	Acetaminophen	S	Unknown	Unk	Not Reported
Personal Independence In	Apo Hydro	S	Unknown	Unk	Not Reported
Daily Activities;	Simponi	S	Subcutaneous		Not Reported
Lymphocyte Count	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Increased; Malaise;	Leflunomide	S	Unknown	200 Unk	Not Reported
Musculoskeletal Stiffness;	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Nasal Congestion;	Humira	S	Subcutaneous	40 Milligram	Not Reported
Nasopharyngitis; Nausea;	Plaquenil [Hydroxychloroquine	S	Oral	200 Mg, Bid	Not Reported
Nephrolithiasis; Neutrophil	Phosphate]				
Count Increased;	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Osteopenia; Pain; Pain In	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, 1 Every 24	Not Reported
Extremity; Peripheral				Hours	
Swelling; Pneumonia;	Apo-Hydroxyquine	S	Unknown	200 Milligram, Bid	Not Reported
Product Use Issue;	Remicade	S	Intravenous (not	200 Milligram	Not Reported
Pyrexia; Rash; Red Blood			otherwise specified)		
Cell Sedimentation Rate	Remicade	S	Intravenous (not	5 Unit	Not Reported
Increased; Red Cell					
Distribution Width					
Increased; Rheumatoid					
Arthritis; Somnolence;					
Synovitis; Therapeutic					
Product Effect Incomplete;					
Tooth Abscess; Treatment					
Failure; Visual Impairment;					
Weight Decreased; White					
Blood Cell Count					
Increased					

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		otherwise specified)		
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Acetaminophen	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Bid	Not Reported
Hydroxychloroquine	S	Oral	200 Milligram, Bid	Not Reported
Doxycycline	S	Unknown	100 Milligram, Bid	Not Reported
Acetaminophen And Codeine Phosphate	S	Unknown	Unk	Not Reported
Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown	20 Nanogram	Not Reported
Diphenhydramine Hydrochloride;Paracetamol	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	25 Dosage Form	Not Reported
Methotrexate	S	Unknown	Unk, Qwk	Not Reported
Meloxicam	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Tylenol W/Codeine	C	Unknown		Not Reported
Celebrex	C	Oral	200 Mg, Bid	Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Celecoxib	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported

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Leflunomide	C	Unknown	20 Milligram, 2 Every 1 Day	Not Reported
Diphenhydramine	C	Oral	50 Milligram	Not Reported
Glyburide (Micronized)	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Lipitor	C	Unknown		Not Reported
Metormin	C	Unknown		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	12913728	EXPEDITED (15-DAY)	HO, OT		CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-091701			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Drug Ineffective; Drug Intolerance; Hypersensitivity; Hypoaesthesia; Infection; Nausea; Nephrolithiasis; Nerve Injury; Neutropenia; Off Label Use; Osteoarthritis; Pain In Extremity; Paraesthesia; Product Use Issue; Pulmonary Congestion; Synovitis; White Blood Cell Count Decreased	Orencia			S	Intravenous (not otherwise specified)	40 Milligram		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk, 152.0 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk, 122 Days		Not Reported
	Humira			S	Subcutaneous	40 Milligram, 2 Every One Week		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported
	Methotrexate			S	Subcutaneous	Unk, 580.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral	400 Milligram, 580.0 Days		Not Reported

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Phosphate]					
Apo-Hydroxyquine	S	Oral	400 Milligram		Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk		Not Reported
Methotrexate	S	Oral	Unk		Not Reported
Naprosyn E	S	Unknown	Unk		Not Reported
Prednisone	S	Unknown	Unk		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	12914292	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092847		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthropathy; Arthropathy; Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4wk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Q4mo		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Humira			S	Unknown	40 Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	12.5 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Qd		Not Reported

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Apo-Hydroxyquine	S	Unknown	200 Milligram, Qd	Not Reported
Methotrexate	S	Oral	12.5 Milligram, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qwk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
Leflunomide	S	Oral	20 Milligram, Cyclical	Not Reported
Leflunomide	S	Unknown	20 Milligram	Not Reported
Leflunomide	S	Unknown	Unk,Qd	Not Reported
Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
Leflunomide	S	Unknown	20 Milligram, Q2wk	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, 1 Every 1 Day	Not Reported
Xeljanz	C	Oral	5 Milligram, Two Time In A Week	Not Reported
Xeljanz	C	Unknown	Unk Unk, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	13153195	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-005339			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Pain; Peripheral Swelling; Rash;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported

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

Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Rocuronium	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
	Pencillin	S	Unknown	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
	Rocuronium Bromide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	13182370	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-17K-028-1856140-00		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Aleve	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Naproxen	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Prednisone Teva	S	Oral	Not Reported
	Plaquenil Sulfate	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	13519381	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038159		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Alopecia;	Orencia			S	Subcutaneous	150 Mg, Qmo		Bristol Myers Squibb	

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Arthropathy; Condition	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Aggravated; Diarrhoea;	Rituxan	S	Intravenous (not	1000 Milligram	Not Reported
Dizziness; Drug			otherwise specified)		
Ineffective; Drug	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Intolerance; Fatigue;	Simponi	S	Subcutaneous	50 Milligram, Qmo	Not Reported
Fibromyalgia;	Methotrexate Sodium	S	Subcutaneous	20 Mg, Qwk	Not Reported
Glossodynia; Hand	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Deformity; Nausea;	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
Oedema; Off Label Use;	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported
Pain; Pemphigus;	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Prescribed Overdose;	Methotrexate	S	Subcutaneous	Unk, Qwk	Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
Synovitis; Systemic Lupus	Celebrex	S	Unknown	200 Milligram	Not Reported
Erythematosis; Vomiting	Naprosyn [Naproxen Sodium]	S	Unknown	500 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1 Gram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	13850192	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-070656			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective;	Orencia	S	Intravenous (not otherwise specified)	750 Milligram, Q4wk,Cyclical	Bristol Myers Squibb
Hypoaesthesia; Impaired Work Ability; Injection Site Reaction; Joint Swelling;	Actemra	S	Unknown	Unk	Not Reported
Malaise; Nodule; Pain;	Arava	S	Unknown	10 Mg, Qd	Not Reported
Product Dose Omission;	Cimzia	S	Subcutaneous	Unk	Not Reported
Rash; Rheumatoid Arthritis; Rheumatoid Nodule; Swelling;	Enbrel	S	Unknown	Unk	Not Reported
Systemic Lupus	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Erythematous Rash;	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Not Reported
Tenosynovitis;	Methotrexate	S	Unknown		Not Reported
Therapeutic Response Decreased; Tooth Disorder; Tooth Infection;	Prednisone	S	Unknown		Not Reported
Weight Decreased	Actonel	C	Unknown	35 Milligram	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
	Risedronate Sodium	C	Unknown	35 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	15163376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2154400		29 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ill-Defined Disorder;	Mycophenolate Mofetil			S	Unknown			Not Reported
Systemic Inflammatory Response Syndrome;	Belimumab			S	Unknown			Not Reported
Ulcer; Vasculitis	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	15418599	EXPEDITED (15-DAY)		OT	DE-JNJFOC- 20180917519		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug	Remicade			S	Intravenous (not otherwise specified)			Janssen

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Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Simponi	S	Subcutaneous		Janssen
	Ciclosporin	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Solution Intravenous	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not		Not Reported

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			otherwise specified)	
Rituximab	S	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Oral	2 Ot	Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	15680209	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2574019-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome;	Humira			S	Subcutaneous			Not Reported
Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo Celecoxib			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celecoxib			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	15702743	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2581224-00		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bronchitis;	Humira			S	Subcutaneous			Not Reported

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Contraindicated Product	Enbrel	S	Unknown		Not Reported
Administered; Cough;	Erythromycin	S	Unknown		Not Reported
Drug Hypersensitivity;	Leflunomide	S	Oral		Not Reported
Drug Ineffective; Drug	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Intolerance; Foot	Methotrexate	S	Oral	Solution	Not Reported
Deformity; Influenza Like	Orencia	S	Unknown		Not Reported
Illness; Interstitial Lung	Sulfasalazine	S	Unknown		Not Reported
Disease; Malaise; Mass	Novo-Rythro	S	Unknown		Not Reported
Excision; Nodule;	Celebrex	C	Unknown		Not Reported
Rheumatoid Arthritis;	Ergocalciferol	C	Unknown		Not Reported
Stress; Therapeutic	Marijuana	C			Not Reported
Product Effect Decreased	Risedronate	C	Oral		Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Hydroxychloroquine	C	Oral		Not Reported
	Bupropion	C	Unknown		Not Reported
	Cannabis Sativa	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	15932044	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2651975-00		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported	
Alopecia; Arthralgia; Blood	Actemra			S	Intravenous (not			Not Reported	
Cholesterol Increased;					otherwise specified)				
Contraindicated Product	Apo-Folic Acid			S	Unknown			Not Reported	
Administered; Drug	Apo-Prednisone			S	Unknown			Not Reported	
Ineffective; General	Arava			S	Unknown			Not Reported	
Physical Health	Cetirizine Hydrochloride			S	Unknown			Not Reported	
Deterioration; Headache;									
Hypersensitivity;	Cetirizine Hydrochloride			S				Not Reported	
Hypertension; Joint	Cetirizine Hydrochloride			S	Unknown			Not Reported	
Swelling; Maternal	W/Pseudoephedrine							Not Reported	
Exposure During									
Pregnancy;									

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Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosis; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Golimumab	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

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

	Etanercept	S	Subcutaneous	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	16396768	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2809469-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	16640871	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-070998			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Rheumatoid Arthritis; Therapeutic	Orencia			S	Unknown			Bristol Myers Squibb	

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

Product Effect Incomplete	Enbrel	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	16724652	EXPEDITED (15-DAY)		HO, OT	PHHY2019CA192974		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown	Unk		Novartis
Abdominal Pain Upper;	Voltaren			S	Unknown			Novartis
Arthropathy; Deafness;	Voltaren			S				Novartis
Deafness Transitory;	Voltaren			S				Novartis
Decreased Appetite;	Voltaren			S				Novartis
Dizziness; Drug	Voltaren			S				Novartis
Hypersensitivity; Ear	Diclofenac Potassium			S	Unknown	Unk		Novartis
Infection; Eating Disorder;	Clopidogrel			S	Unknown	Unk		Not Reported
Feeding Disorder;	Clopidogrel			S				Not Reported
Functional Gastrointestinal	Clopidogrel			S				Not Reported
Disorder; Gastrointestinal	Clopidogrel			S				Not Reported
Disorder; Gastrointestinal	Clopidogrel			S				Not Reported
Pain; Headache;	Methotrexate			S	Unknown	Unk		Not Reported
Hypophagia;	Methotrexate			S				Not Reported
Musculoskeletal Disorder;	Methotrexate			S				Not Reported
Nausea; Off Label Use;	Methotrexate			S				Not Reported
Pharyngitis; Vomiting;	Vitamin C			S	Unknown	Unk		Not Reported
Weight Decreased	Arava			S	Oral	Unk		Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Arava			S				Not Reported
	Asa			S	Unknown	325 Mg (Delayed Release)		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

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

Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Motrin	S	Unknown	Unk	Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Motrin	S			Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Topical		Not Reported
Aspirin	S	Unknown		Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Aspirin	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Ibuprofen	S	Unknown		Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Trimethoprim	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	16841034	EXPEDITED (15-DAY)		OT	GR-BAUSCH-BL-2019-026015		59 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Hyperparathyroidism	Ramipril	S	Unknown	Not Reported
Secondary; Osteoporosis;	Prednisolone	S	Unknown	Bausch And Lomb
Rib Fracture; Upper	Metformin Hydrochloride	S	Unknown	Santarus
Respiratory Tract Infection	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lansoprazole	S	Unknown	Not Reported
	Belimumab	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Exemestane	S	Unknown	Not Reported
	Thyroxine	S	Oral	Not Reported
	Thyroxine	S	Unknown	Not Reported
	Dicumarol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	16886720	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2946845-00		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported
Alopecia; Anti-Cyclic	Leflunomide			S	Oral			Not Reported
Citrullinated Peptide	Tofacitinib Citrate			S	Unknown			Not Reported
Antibody Positive;	Sulfasalazine			S	Oral			Not Reported
Arthropathy; Condition	Sulfasalazine			S	Oral			Not Reported
Aggravated;	Tofacitinib			S	Unknown			Not Reported
Contraindicated Product	Sulfathalidine			S	Oral			Not Reported
Administered; Discomfort;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Drug Ineffective; Drug	Orencia			S	Subcutaneous			Not Reported
Intolerance; Duodenal	Actemra			S	Subcutaneous			Not Reported
Ulcer Perforation; Fatigue;	Cortisone			S	Topical			Not Reported
Glossodynia; Hand	Apo-Prednisone			S	Oral			Not Reported
Deformity; Helicobacter	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Infection; Hepatic Enzyme								
Increased; Hip								
Arthroplasty;								
Hypersensitivity; Infusion								
Related Reaction; Knee								
Arthroplasty; Maternal								

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

Exposure During	Hydroxychloroquine	S	Oral	Not Reported
Pregnancy; Pain;	Folic Acid	S	Unknown	Not Reported
Pemphigus; Pericarditis;	Folic Acid	S	Unknown	Not Reported
Rash; Rheumatoid	Folic Acid	S	Unknown	Not Reported
Arthritis; Rheumatoid	Folic Acid	S	Unknown	Not Reported
Factor Positive; Swelling;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Synovitis; Systemic Lupus	Remicade	S	Unknown Powder For Infusion	Not Reported
Erythematosis; Treatment	Cetirizine	S	Unknown	Not Reported
Failure; Wound	Enbrel	S	Subcutaneous	Not Reported
	Methotrexat	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Cimzia	S	Subcutaneous Single-Use Pre-Filled Syringe	Not Reported
	Arava	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	W/Pseudoephedrine	S	Cutaneous	Not Reported
	Topicort (Hydrocortisone Acetate)	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Desoximetasone	S	Ophthalmic	Not Reported
	Diclofenac	S	Oral	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported

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

Golimumab	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Acetaminophen	S	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	6965678	EXPEDITED (15-DAY)		OT	DE-RANBAXY-2009RR-23202		42 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Immune Reconstitution Inflammatory Syndrome	Ceftriaxone			S	Unknown	Unk		Not Reported
	Co-Trimoxazole			S	Unknown	Unk		Mutual
	Doxycycline Hydrochloride			S	Unknown	Unk		Sun
	Hydroxychloroquine Sulphate-Bp			S	Unknown	Unk		Sun
	Streptomycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17260297	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017687			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported

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

Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Dorzolamide ,Timolol	S	Unknown	1 Df, Bid	Apotex
	Dorzolamide ,Timolol	S	Unknown	Unk Unk, Bid	Apotex
	Ramipril	S	Oral	Unk, Qd	Apotex
	Ramipril	S	Oral	Unk	Apotex
	Actemra	S	Unknown		Not Reported
	Levothyroxine	S	Unknown	1 Df, Unk	Not Reported
	Levothyroxine	S	Unknown	Unk, Qd	Not Reported
	Tylenol /00020001/	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Endocervical	400 Mg, Qd	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Dorzolamide Hydrochloride W/Timolol Maleate	C	Ophthalmic	Unk, Bid	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Levothyroxine	C	Unknown	One Once A Day	Not Reported
	Prednisone	C	Unknown	7 Mg, Qd	Not Reported
	Ramipril	C	Unknown	One Once A Day	Not Reported
	Tylenol No.2	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17332504	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-004133		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; C-Reactive Protein Increased; Colitis	Orencia			S	Unknown			Bristol Myers Squibb	

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

Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown	50 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Dorzolamide	C	Unknown	Unk, Bid	Not Reported
	Hydrochloride/Timolol Maleate	C	Unknown	Unk, Qwk	Not Reported
	Ergocalciferol	C	Unknown	0.6 Percent, Tid	Not Reported
	Estrogel	C	Unknown	40 Milligram, Qd	Not Reported
	Furosemide	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown	1500 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	320 Milligram, Qd	Not Reported
	Xalatan	C	Unknown	50 Microgram, Qd	Not Reported
	Zingiber Officinale	C	Unknown	500 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17517039	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200243785			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug-Induced Liver Injury; Liver Function Test Increased; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Uveitis	Stelara			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Simponi			S	Subcutaneous			Janssen	
	Cimzia			S	Subcutaneous			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Otezla			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Sulfasalazine			S				Not Reported	

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

Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Naprosyn /00256201/	S	Unknown	Not Reported
Piroxicam	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Tocilizumab	S	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Codeine	C	Subcutaneous	Not Reported
Imuran /00001501/	C	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17577763	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200329927		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis; Arthralgia; Back Injury; Back Pain; Chest Pain; Contraindicated	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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

Product Administered;	Gold	S	Unknown	Not Reported
Diarrhoea; Drug	Humira	S	Subcutaneous	Not Reported
Hypersensitivity; Drug	Methotrexate	S	Oral	Not Reported
Ineffective; Drug	Orencia	S	Subcutaneous	Not Reported
Intolerance; Headache;	Penicillamine	S		Not Reported
Hypersensitivity;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Inflammation;				
Intervertebral Disc Compression;	Prednisone	S		Not Reported
Intervertebral Disc Space Narrowing; Joint Stiffness;	Prednisone	S	Unknown	Not Reported
Joint Swelling; Malaise;	Hydroxychloroquine	S	Unknown	Not Reported
Musculoskeletal Pain;				
Musculoskeletal Stiffness;	Azathioprine	C		Not Reported
Nausea; Neck Pain; Pain;	Cyclophosphamide	C		Not Reported
Peripheral Swelling;	Docusate Sodium	C		Not Reported
Proteinuria; Rheumatoid	Doxycycline	C	Oral	Not Reported
Arthritis; Swelling;	Elavil /00002202/	C	Unknown	Not Reported
Treatment Failure;	Sulfasalazine	C	Oral	Not Reported
Vasculitis	Tobramycin	C	Intraocular	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17579767	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327866		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered;	Simponi			S	Subcutaneous			Janssen	
Drug Ineffective;	Remicade			S	Intravenous (not otherwise specified)			Janssen	
Headache; Hepatotoxicity;	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg		Not Reported	
Insomnia; Joint Swelling;	Anakinra			S	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported	
Memory Impairment; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Etanercept			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Methotrexate	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Insulin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17579770	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200327863		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Simponi			S	Subcutaneous			Janssen
Constipation; Diarrhoea;	Arava			S	Unknown			Not Reported
Dizziness; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Hypersensitivity; Drug	Hydroxychloroquine Sulfate			S				Not Reported
Ineffective; Drug	Orencia			S	Unknown			Not Reported
Intolerance; Fatigue;	Sulfasalazine			S	Unknown			Not Reported
Fibromyalgia;	Enbrel			S	Unknown			Not Reported
Hypersensitivity; Insomnia;	Enbrel			S				Not Reported
Iodine Allergy; Nausea;	Methotrexate			S	Subcutaneous			Not Reported
Oedema; Off Label Use;								
Pain; Product Use In								
Unapproved Indication;								

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

Product Use Issue; Rheumatoid Arthritis; Synovitis; Vomiting	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Venlafaxine	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	M-Eslon	C	Unknown	Not Reported
	Morphine	C		Not Reported
	Morphine Sulfate	C	Unknown	Not Reported
	Statex	C	Unknown	Not Reported
	Hydrodiuril	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Naprosyn /00256201/	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17579772	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200327858		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17579773	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200327868		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Anaphylactic Shock;	Simponi	S	Subcutaneous	Janssen
Arthralgia; Bedridden;	Actemra	S	Unknown	Not Reported
Condition Aggravated;	Actonel	S		Not Reported
Contraindicated Product	Celebrex	S	Oral	Not Reported
Administered; Drug	Cimzia	S	Subcutaneous	Not Reported
Ineffective; Fibromyalgia;	Enbrel	S	Subcutaneous	Not Reported
Foot Fracture; General	Leflunomide	S	Oral	Not Reported
Physical Health	Leflunomide	S		Not Reported
Deterioration; Hepatitis;	Methotrexate	S	Subcutaneous	Not Reported
Loss Of Personal	Methotrexate	S	Unknown	Not Reported
Independence In Daily	Orencia	S	Unknown	Not Reported
Activities; Lower Limb	Prednisolone	S	Unknown	Not Reported
Fracture; Mobility	Prednisone	S	Unknown	Not Reported
Decreased; Myocardial	Prolia	S	Subcutaneous	Not Reported
Infarction; Osteoporosis;	Sulfasalazine	S	Oral	Not Reported
Rheumatoid Arthritis;	Sulfasalazine	S	Oral	Not Reported
Therapeutic Product Effect	Leflunomide	S	Oral	Not Reported
Incomplete; Treatment	Minims Prednisolone Sodium	S	Ophthalmic	0.5%
Failure	Phosphate			
	Arava	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Cyclobenzaprime	C		Not Reported
	Desoximetasone	C		Not Reported
	Prednisone Acetate	C		Not Reported
	Tylenol /00020001/	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17605649	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332785		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankylosing Spondylitis;	Simponi			S	Subcutaneous			Janssen	

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

Arthralgia; Arthropathy; Drug Intolerance; Joint Swelling; Knee Arthroplasty; Therapeutic Product Effect Decreased; Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Arava	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S		Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab Xeljanz	S C		Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17605713	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200332775		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Ankle Fracture; Contraindicated Product Administered; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Unevaluable Event; Vomiting	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral	For 3 Years		Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown	11 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral	4 Years		Not Reported

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

Hydroxychloroquine	S	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Plaquenil /00072602/	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Codeine Phosphate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Pregabalin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17616081	EXPEDITED (15-DAY)		DE, HO	BR-ADVANSZ PHARMA-202003002042			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Drug Ineffective; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623454	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340457		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Fluctuation; Blood Pressure Increased; Colitis; Dental Caries; Diabetes Mellitus	Simponi			S	Subcutaneous			Janssen
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Hypertension; Musculoskeletal Stiffness; Nausea; Off Label Use;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Amlodipine Besilate			S	Oral			Not Reported
	Asacol			S	Unknown			Not Reported
	Diamicron			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Vitamin D Deficiency; Weight Decreased; Weight Increased	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Atacand Plus	C	Unknown	Not Reported
	Bisoprolol Fumarate	C	Unknown	Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Diphenhydramine	C	Oral	Not Reported
	Ebastine	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623463	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200342096		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product	Simponi			S	Subcutaneous			Janssen
Administered; Drug	Simponi			S				Janssen
Ineffective; Drug	Remicade			S	Intravenous (not otherwise specified)			Janssen
Intolerance; Fatigue;								
Irritable Bowel Syndrome;								

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

Malaise; Nausea; Stress	Apo-Leflunomide	S	Unknown	1.0 Dosage Forms	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Advil /00044201/	C	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tylenol /00020001/	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623466	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340460		48 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Hypertension; Impaired Work Ability; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	

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Decreased; Tuberculin Test Positive	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623532	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340124		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Simponi			S	Subcutaneous			Janssen	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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

Orencia	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Cyclobenzaprine	C	Oral	Not Reported
Cyclobenzaprine	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Leflunomide	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone Acetate	C	Unknown	Not Reported
Tylenol /00020001/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623533	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340125		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Back Pain; Bursitis; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Dry Mouth; Facet Joint Syndrome; Headache; Inflammation; Joint Range Of Motion Decreased; Joint Swelling; Lip Dry; Liver Disorder; Lung Disorder; Muscle Spasms; Musculoskeletal Pain; Musculoskeletal Stiffness; Night Sweats; Obesity; Oedema; Oedema Peripheral; Off Label Use; Osteoarthritis; Pain; Pain In Extremity; Paraesthesia; Peripheral Swelling; Peripheral Venous Disease; Red Blood Cell Sedimentation	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Asa			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Ultracet			C				Not Reported
	Calcite D			C	Unknown			Not Reported
	Citalopram			C				Not Reported
	Domperidone			C	Unknown			Not Reported

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

Rate Abnormal; Rheumatic Fever; Swelling; Synovitis	Folic Acid	C	Unknown	Not Reported
	Gabapentin	C		Not Reported
	Gliclazide	C	Unknown	Not Reported
	Lipitor	C		Not Reported
	Nifedipine	C		Not Reported
	Pantoloc /01263204/	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Risedronate	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340129		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Blood	Simponi			S	Subcutaneous			Janssen
Creatinine Increased;	Actemra			S	Unknown			Not Reported
Diarrhoea; Drug	Arava			S	Unknown			Not Reported
Ineffective; Limb	Enbrel			S	Unknown			Not Reported
Discomfort;	Gold			S	Unknown			Not Reported
Musculoskeletal	Hydroxychloroquine			S	Unknown			Not Reported
Discomfort; Off Label Use;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Pain; Pharyngeal	Orencia			S				Not Reported
Oedema; Rheumatoid	Penicilline G /00000901/			S	Unknown			Not Reported
Arthritis; Therapeutic	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Product Effect Decreased	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623540	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340132			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17623542	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200340452		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Hydroxychloroquine Sulfate Methotrexate Orencia Rituximab Sodium Aurothiomalate Sulfasalazine	S S S S S S	Unknown Subcutaneous Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intramuscular Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17666231	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029672		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Orencia Actemra Arava Codeine Enbrel Humira Hydroxychloroquine Methotrexate Remicade Rituxan Rocuronium Bromide Prednisone			S S S S S S S S S S S S C	Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown			Bristol Myers Squibb Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17672252	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200413057		71 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17681010	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100512			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Actemra			S	Intravenous (not			Not Reported

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		otherwise specified)	
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Humira	S	Subcutaneous	Not Reported
Naproxen	C	Unknown 500 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17686409	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2020TUS018625			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Dexilant			S	Oral	60 Milligram, Qd		Takeda
Antinuclear Antibody Positive; Arthralgia;	Colchicine			S	Unknown	Unk		Takeda
Arthritis; Blister; Dry Mouth; Headache;	Estrogel			S	Topical	Unk Unk, Qd		Not Reported
Hypersensitivity Vasculitis;	Arava			S	Unknown	Unk		Not Reported
Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling;	Belimumab			S	Unknown	Unk		Not Reported
Lymphadenopathy; Menorrhagia;	Breo Ellipta			S	Respiratory (inhalation)	Unk		Not Reported
Musculoskeletal Stiffness;	Celebrex			S	Unknown	Unk		Not Reported
Myalgia; Nausea; Parotid Gland Enlargement;	Meloxicam			S	Unknown	Unk		Not Reported
Peripheral Swelling;	Methotrexate			S	Oral	Unk		Not Reported
Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Milligram, Bid		Not Reported
	Prednisone			S	Unknown	50 Milligram		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Ventolin Hfa			S	Respiratory (inhalation)	Unk		Not Reported

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17686802	EXPEDITED (15-DAY)		OT	JP-LAURUS LABS LIMITED-202000088		41 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Placenta Accreta	Hydroxychloroquine			S	Unknown			Unknown	
	Prednisolone			C	Unknown			Not Reported	
	Tacrolimus			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17686999	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585020		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cataract; Drug Intolerance; Herpes Zoster; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous drip			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Lyrica			C				Not Reported	
	Prednisone			C				Not Reported	
	Xeljanz			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687219	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-244391			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Anxiety; Nightmare; Product Use In	Azithromycin	S	Oral	500 Milligram, Daily	Sun
Unapproved Indication; Psychomotor Hyperactivity	Plaquenil 200 Mg, Comprime Enrobe	S	Oral	600 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687411	EXPEDITED (15-DAY)		OT	DE-TEVA-2020-DE-1224814		45 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Granuloma Skin; Mycobacterium Marinum Infection	Leflunomide			S	Unknown			Barr	
	Prednisolone			S	Unknown	Low-Dose		Actavis	
	Prednisolone			S	Unknown			Actavis	
	Prednisolone			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Hydroxychloroquine			S	Unknown			Teva	
	Sulfasalazine			S	Unknown			Not Reported	
	Amlodipine			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687714	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100422		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi	
	Arava			S	Unknown	20 Mg, Qd		Sanofi	
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported	
	Prednisone			S	Oral	5 Mg, Qd		Not Reported	
	Sulfasalazine			S	Unknown	1000 Mg, Bid		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	20 Mg, Qd		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100732			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qd		Not Reported
	Arava			S				Sanofi
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687716	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100909		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Hydroxychloroquine Sulfate			S		100 Mg		Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline			S				Not Reported
Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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Xeljanz			S		5 Mg, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687718	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100689			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Ineffective; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Hydroxychloroquine			S				Sanofi	
	Arava			S				Sanofi	
	Celecoxib			S	Oral	200 Mg, Bid		Not Reported	
	Actemra			S				Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S				Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687719	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100913		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Infection; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate			S	Oral	300 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S		1 Df, Qd		Sanofi	
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi	
	Methotrexate			S	Subcutaneous	17.5 Mg		Not Reported	
	Risedronate Sodium			S				Not Reported	
	Risedronate Sodium			S	Oral	35 Mg, Qw		Not Reported	
	Actemra			S				Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	35 Mg		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported	
	Hydroxychloroquine Sulfate			C				Not Reported	

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21-Apr-2020	17687721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100758		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug	Plaquenil			S				Sanofi	
Ineffective; Infection;	Arava			S				Sanofi	
Malaise; Nasopharyngitis;	Methotrexate			S				Not Reported	
Product Dose Omission;	Simponi			S				Not Reported	
Rheumatoid Arthritis;	Naproxen			C				Not Reported	
Tendon Rupture									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687722	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100911		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi	
Intolerance; Non-	Arava			S				Sanofi	
Hodgkin'S Lymphoma	Methotrexate			S		25 Mg		Not Reported	
	Minocycline Hydrochloride			S				Not Reported	
	Sulfasalazine			S				Not Reported	
	Apo-Azathioprine			S		100 Mg		Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Amoxicillin And Clavulanate			C				Not Reported	
	Potassium								
	Amoxil [Amoxicillin]			C				Not Reported	
	Bcg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687786	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101019			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S		200 Mg	Sanofi
	Leflunomide	S		10 Mg, Qd	Sanofi
	Methotrexate	S		15 Mg	Not Reported
	Actemra	S		Unk	Not Reported
	Enbrel	S		Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Orencia	S		Unk	Not Reported
	Remicade	S		Unk	Not Reported
	Rituximab	S		Unk	Not Reported
	Arava	C		Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Oral	200 Mg, Bid	Not Reported
	Prednisone	C			Not Reported
	Simponi	C			Not Reported
	Xeljanz	C	Oral	5 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687792	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100987			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritits; Skin Lesion; Uveitis	Plaquenil			S	Unknown			Sanofi
	Aralen			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687797	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA101046		3 YR	Female	CAN

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Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Hydroxychloroquine Sulfate			S	Oral	5 Mg		Sanofi
	Methotrexate			S		15 Mg/M2, Qow		Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
	Prednisone			S		Unk		Not Reported
	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
	Triamcinolone Acetonide			S				Sanofi
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qow		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
	Anakinra			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S		1.5 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Immune Globulin (Immunoglobulins Nos)			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	30 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
	Triamcinolone Hexacetonide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687801	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101230			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S		20 Mg, Qd		Sanofi
	Meloxicam			S	Oral	7.5 Mg		Not Reported

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Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Actemra	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Sulfasalazine	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688091	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2020M1040433		21 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Compartment Syndrome; Acute	Prednisolone			S	Intravenous (not otherwise specified)	Pulse Therapy		Not Reported	
Respiratory Distress Syndrome; Drug	Prednisolone			S	Oral	Unk		Not Reported	
Ineffective; Pancreatitis	Hydroxychloroquine			S	Unknown			Mylan	
Necrotising; Sepsis; Shock Haemorrhagic	Plasma			S	Unknown			Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584496		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug	Rituxan			S	Intravenous drip			Not Reported	
Ineffective; Drug	Apo-Leflunomide			S	Unknown			Not Reported	
Intolerance; Lymphoma	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Desoximetasone			C	Unknown			Not Reported	

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Diclofenac	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688210	EXPEDITED (15-DAY)	OT		NVSC2020IT104815		52 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Drug Interaction; Hepatic Failure; Pneumonia Viral; Product Use In Unapproved Indication	Tacrolimus			S	Unknown	Unk		Novartis
	Tacrolimus			S				Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ritonavir			S	Unknown	Unk		Not Reported
	Ritonavir			S				Not Reported
	Mycophenolate Mofetil			C	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Darunavir			C	Unknown	Unk		Not Reported
	Darunavir			C				Not Reported
	Cobicistat			C	Unknown	Unk		Not Reported
	Cobicistat			C				Not Reported
	Colchicine			C	Unknown	1 Mg On Day 8		Not Reported
	Colchicine			C	Unknown	0.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688319	NON-EXPEDITED			US-CELGENEUS-USA-20200404981			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Diarrhoea; Headache	Otezla			S	Oral	60 Milligram		Celgene
	Synthroid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Cosentyx			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported

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Vitamin D	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Effexor	C	Unknown	Not Reported
Baby Aspirin	C	Unknown	Not Reported
Prilosec	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Femara	C	Unknown	Not Reported
Prozosin	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Doxorubicin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688557	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANSZ PHARMA-202003002806			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Failure; Off Label Use; Organ Failure; Septic Shock	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Rocephine			C		Unk		Not Reported
	Etomidate			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Suxamethonium			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688648	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1225642		21 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Hidroxicloroquina (2143a)			S	Oral	400mg/24h		Teva
	Linezolid (1279a)			S	Intravenous (not otherwise specified)			Teva
	Ambisome 50 Mg Polvo Para Dispersion Para Perfusion , 10			S	Intravenous (not otherwise specified)			Not Reported

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Viales
Tocilizumab (8289a) S Intravenous (not otherwise specified) Unknown Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688686	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13364		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty	Infliximab			S	Unknown	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown		Not Reported
	Hydroxychloroquine			S	Unknown	Unknown		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported
	Orencia			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Simponi			S	Subcutaneous	Unknown		Not Reported
	Sulfasalazine			S	Oral	Unknown		Not Reported
	Tocilizumab			S	Unknown	Unknown		Not Reported
	Desoximetasone			C	Unknown	Unknown		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688704	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA-202004002845			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Blindness; Cataract	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd		Concordia

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				(Coated Tablet)	
Depakote	C	Unk	Not Reported		
Ozempic	C	Unk	Not Reported		
Selozok	C	Unk	Not Reported		
Pressetina	C	Unk	Not Reported		
Glifage	C	Unk	Not Reported		
Zetia	C	Unk	Not Reported		
Rosuvastatina	C	Unk	Not Reported		
Marevan	C	Unk	Not Reported		
Topiramato	C	Unk	Not Reported		
Venlafaxine	C	Unk	Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688866	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100693			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Arava			S	Oral	200 Mg, Qd (1 Df, Every 1 Day)		Sanofi
	Bisoprolol Salt Not Specified			S				Not Reported
	Cefaclor			S				Not Reported
	Celecoxib			S				Not Reported
	Demerol			S				Sanofi
	Erythromycin			S				Sanofi
	Erythromycin			S				Sanofi
	Levofloxacin			S				Not Reported
	Pregabalin			S				Not Reported
	Methotrexate			S				Not Reported
	Metronidazole			S				Sanofi
	Norfloxacin			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S				Not Reported

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Arthrotec	S							Not Reported
Humira	S	Subcutaneous	400 Mg					Not Reported
Meperidine Hydrochloride	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100832			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S		Unk		Sanofi
	Chloroquine Sulfate			S				Sanofi
	Myochrysine			S				Not Reported
	Humira			S				Not Reported
	Remicade			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688869	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100754			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S		50 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100853			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil	S	Unknown	Sanofi
	Aralen	S	Unknown	Sanofi
	Leflunomide	S	Unknown	Sanofi
	Methotrexate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688872	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100674		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Leflunomide			S				Sanofi
	Orencia			S				Not Reported
	Xeljanz			S				Not Reported
	Actemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone			C		Unk Unk, Bid		Not Reported
	Pantoloc [Pantoprazole]			C				Not Reported
	Prednisone			C		20 Mg, Qd		Not Reported
	Xarelto			C				Not Reported
	Tylenol 8 Hr Arthritis Pain			C		2 Df, Bid		Not Reported
	Calcium & Vitamin D3			C				Not Reported

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21-Apr-2020	17688879	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200421346		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen

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Ineffective; Nausea; Oral Discomfort; Product Use Issue; Uveitis	Adalimumab	S	Subcutaneous	Not Reported
	Leflunomide	S		Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Sarilumab	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S		Not Reported
	Tocilizumab	S		Not Reported
	Tofacitinib	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	C		Not Reported
	Rabeprazole Sodium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688898	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-13469			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Infliximab			S	Unknown	Unknown		Not Reported	
	Actemra			S	Unknown	Unknown		Not Reported	
	Anakinra			S	Unknown	Unknown		Not Reported	
	Enbrel			S	Subcutaneous	Unknown		Not Reported	
	Humira			S	Unknown	Unknown		Not Reported	
	Humira			S	Subcutaneous	Unknown; Solution Subcutaneous		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	

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Orencia	S	Unknown	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown; Powder For Solution Intravenous	Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Sulfasalazine	S	Oral	Unknown	Not Reported
Methotrexate	C	Oral		Not Reported
Desoximetasona	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688907	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101008		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Oral	200 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Unk		Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported

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	Xeljanz	S	Oral	5 Mg				Not Reported
	Sulfasalazine	C	Unknown					Not Reported
	Wellbutrin	C	Oral					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688909	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100917			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Sanofi
	Arava			S				Sanofi
	Methotrexate			S	Oral	25 Mg,Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S		50 Mg,Qw		Not Reported
	Myochrysine			S		25 Mg,Qw		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688918	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101017			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S				Not Reported
	Enbrel			S				Not Reported
	Actemra			S				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688919	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100879			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosus; Transaminases Increased; Treatment Failure	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Sanofi
	Arava	S	Oral	20 Mg, Qd	Sanofi
	Azathioprine	S			Not Reported
	Myochrysine	S	Intramuscular		Not Reported
	Sulfasalazine	S			Not Reported
	Orencia	S	Subcutaneous	125 Mg, Qw	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
	Pariet	C		20 Mg, Qd	Not Reported
	Folic Acid	C		5 Mg, Qd; 1 Every 1 Days	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688920	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100863			Female	CAN

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

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689015	DIRECT	Y	DE			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689055	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226544		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Daily;		Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Risedronate Sodium			S	Oral			Teva	
	Actemra			S	Subcutaneous			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram Daily;		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689154	EXPEDITED (15-DAY)		CA, DS, OT	FR-UCBSA-8027844			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Keppra			S		3000mg Daily		Not Reported
	Keppra			S	Transplacental	Unk		Not Reported
	Trileptal			S	Transplacental			Not Reported
	Plaquenil			S	Transplacental			Not Reported
	Paracetamol			S	Transplacental			Not Reported
	Cortancyl			C	Transplacental			Not Reported
	Actonel			C	Transplacental			Not Reported
	Orocal D3			C	Transplacental			Not Reported
	Diffu-K			C	Transplacental			Not Reported
	Speciafoldine			C	Transplacental			Not Reported
	Kaleorid			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225072			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Neutropenia; Rash; White Blood Cell Count Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown	20 Mg, 1 Every 1 Week		Barr
	Plaquenil			S	Unknown			Not Reported

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Xeljanz			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689616	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1224923			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Fatigue; Rheumatoid Arthritis; Weight Increased	Indometacin			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Morphine Sulfate			S	Unknown			Actavis	
	Prednisone			S	Unknown	12.5 Milligram Daily;		Actavis	
	Acetaminophen			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689685	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226003		66 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Amoxicilina / Clavulanico (Amoxicillin\Clavulanic Acid)			S	Oral	875 Mg,1 Df		Teva	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689693	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016133US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported	
	Azithromycine Sandoz [Azithromycin Monohydrate]			S	Oral	250 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689715	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101218			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Abnormal; Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S				Sanofi	
	Bisoprolol Fumarate			S				Not Reported	
	Cefixime			S				Not Reported	
	Methotrexate			S				Not Reported	
	Morphine Hydrochloride			S				Not Reported	
	Nifedipine			S				Not Reported	
	Pantoprazole			S				Not Reported	
	Prednisone			S				Not Reported	
	Clonazepam			S				Not Reported	
	Zantac			S				Sanofi	
	Zopiclone			S				Not Reported	
	Azathioprine			S	Oral	100 Mg		Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689717	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101219			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi	

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Leflunomide	S	Unknown	10 Mg, Qd	Sanofi
Methotrexate	S	Unknown	15 Mg	Not Reported
Etanercept	S	Unknown		Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689721	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100822			Female	CAN

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

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21-Apr-2020	17689724	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101252			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		10 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Cosentyx			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow, Solution Subcutaneous		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S				Not Reported
	Penicillin G [Benzylpenicillin]			S				Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qm, Solution Subcutaneous		Not Reported
	Stelara			S		Unk, Q8w		Not Reported
	Stelara			S	Subcutaneous	Unk, Solution Subcutaneous		Not Reported
	Cetirizine			C		10 Mg, Bid		Not Reported
	Enbrel			C		50 Mg, Qw		Not Reported
	Lasix [Furosemide]			C		40 Mg, Qm		Not Reported
	Montelukast			C		10 Mg, Qd		Not Reported
	Synthroid			C		75 Mg, Qd		Not Reported
	Terbutaline Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689729	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101216			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi

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Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam Methotrexate Actemra Enbrel Humira Sulfasalazine	S S S S S C	Oral Oral Subcutaneous Subcutaneous Subcutaneous Oral	7.5 Mg 20 Mg, Qw 1 Df, Qw 50 Mg, Qw	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689730	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101215			Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689734	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101213		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal;	Hydroxychloroquine Sulfate Arava Sodium Aurothiomalate Methotrexate Actemra Enbrel			S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown	200 Mg, Bid 20 Mg, Qd 25 Mg, Qd 25 Mg		Sanofi Sanofi Not Reported Not Reported Not Reported Not Reported

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

Peripheral Swelling;	Orencia	S	Unknown		Not Reported
Pneumonia Viral; Soft	Remicade	S	Intravenous (not	300 Mg	Not Reported
Tissue Disorder; Synovitis;			otherwise specified)		
Therapeutic Product Effect	Xeljanz	S	Unknown		Not Reported
Incomplete	Humira	S	Subcutaneous	40 Mg	Not Reported
	Acetaminophen	C			Not Reported
	Anakinra	C	Unknown	100 Mg	Not Reported
	Ativan	C			Not Reported
	Codeine	C			Not Reported
	Darifenacine	C			Not Reported
	Desoximetasone	C			Not Reported
	Dilaudid	C			Not Reported
	Diphenhydramine	C			Not Reported
	Furosemide	C			Not Reported
	Hydromorphone	C			Not Reported
	Kadian	C			Not Reported
	Kenalog [Triamcinolone	C	Unknown	40 Mg	Not Reported
	Acetonide]				
	Loperamide	C			Not Reported
	Norflex [Orphenadrine Citrate]	C			Not Reported
	Omniaris	C			Not Reported
	Oxyneo	C			Not Reported
	Pantoprazole	C			Not Reported
	Restasis	C			Not Reported
	Rituximab	C	Intravenous (not		Not Reported
			otherwise specified)		
	Synthroid	C			Not Reported
	Trimethoprim	C			Not Reported
	Urispas	C	Unknown	200 Mg	Not Reported
	Vagifem	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689790	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1225158		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Density Decreased; Cataract;	Leflunomide			S	Unknown			Barr	



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

Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Joint Range Of Motion Decreased; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo- Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide Methotrexate Actemra Gold Humira Hydroxychloroquine Mobicox Orencia Depo-Medrol Diclofenac Hydroxychloroquine Sulfate Pantoprazole Magnesium Prednisone Xeljanz	S S S S S S S S C C C C C C	Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Oral	20 Mg, 1 Every 1 Week 80 Milligram Daily; Suspension Intraarticular 10 Milligram Daily;	Barr Barr Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689979	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2609900-00			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Arava			C				Not Reported	
	Celebrex			C				Not Reported	
	Folic Acid			C				Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17690106	EXPEDITED (15-DAY)		DS, OT	NVSC2020CA102627		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren			S	Unknown	Unk		Novartis
	Diclofenac			S	Unknown	Unk		Novartis
	Diclofenac Potassium			S	Unknown	Unk		Novartis
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17690600	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2020-019705		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17690705	EXPEDITED (15-DAY)		HO	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-244413		35 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Rash	Ciprofloxacin			S	Unknown	800 Milligram, Daily		Ranbaxy	
	Doxycycline			S	Oral	Unk		Sun	
	Hydroxychloroquine			S	Oral	600 Milligram, Daily		Sun	
	Moxifloxacin			S	Oral	400 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17690772	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1226789		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Risedronate			S	Oral			Teva	
	Risedronate			S	Unknown			Teva	
	Actemra			S	Subcutaneous			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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

	Hydroxychloroquine Sulfate	S	Unknown				Not Reported
	Hydroxychloroquine Sulfate	S	Oral	300 Milligram Daily;			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown				Not Reported
	Orencia	S	Intravenous (not otherwise specified)				Not Reported
	Remicade	S	Intravenous (not otherwise specified)				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)				Not Reported
	Simponi	S	Subcutaneous				Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	11607841	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-JNJFOC-20150923280		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Simponi			S	Subcutaneous			Janssen
Adjustment Disorder With	Stelara			S	Subcutaneous			Janssen
Depressed Mood; Adverse	Remicade			S	Intravenous (not otherwise specified)			Janssen
Event; Alopecia; Amnesia;	Zyrtec			S	Oral			Johnson And Johnson
Anti-Cyclic Citrullinated	Zyrtec			S	Unknown			Johnson And Johnson
Peptide Antibody Positive;	Reactine (Cetirizine			S	Oral			Johnson And Johnson
Arthropathy; Blister;	Dihydrochloride)			S	Oral			Not Reported
Breast Cancer Stage Iii;	Methotrexate			S	Oral			Not Reported
Condition Aggravated;	Methotrexate			S	Oral			Not Reported
Contraindicated Product	Methotrexate			S	Unknown			Not Reported
Administered; Delirium;	Methotrexate			S	Oral			Not Reported
Depression; Diarrhoea;	Methotrexate			S	Intra-arterial			Not Reported
Disability; Discomfort;	Folic Acid			S	Unknown			Not Reported
Dislocation Of Vertebra;	Folic Acid			S	Unknown			Not Reported
Drug Hypersensitivity;								
Drug Ineffective; Drug								
Intolerance; Drug								
Tolerance Decreased;								
Duodenal Ulcer								
Perforation; Exposure								
During Pregnancy;								

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

Fatigue; Gait Disturbance;	Folic Acid	S	Unknown		Not Reported
General Physical Health Deterioration;	Folic Acid	S	Unknown		Not Reported
Glossodynia; Glossodynia;	Actemra	S	Subcutaneous		Not Reported
Grip Strength Decreased;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Hand Deformity;					
Helicobacter Infection;	Arava	S	Oral		Not Reported
Hepatic Enzyme Increased; Hip	Cimzia	S	Subcutaneous		Not Reported
Arthroplasty;	Enbrel	S	Subcutaneous		Not Reported
Hypersensitivity; Infection;	Prednisone	S	Oral		Not Reported
Infusion Related Reaction;	Prednisone	S	Unknown		Not Reported
Joint Range Of Motion Decreased; Joint Swelling;	Humira	S	Subcutaneous		Not Reported
Knee Arthroplasty;	Humira	S	Sunconjunctival		Not Reported
Memory Impairment;	Orencia	S	Intravenous (not otherwise specified)	Therpay Duration 11 Monts	Not Reported
Mobility Decreased;	Orencia	S	Subcutaneous		Not Reported
Muscular Weakness; Off Label Use; Pain; Pain In	Fosamax	S	Oral		Not Reported
Extremity; Pemphigus;	Plaquenil	S	Oral		Not Reported
Pericarditis; Peripheral Swelling; Product Use In	Rituxan	S	Intravenous (not otherwise specified)	Solution For Injection/Infusion	Not Reported
Unapproved Indication;	Rituxan	S	Intravesical	Solution For Injection/Infusion	Not Reported
Product Use Issue; Rash;					
Rheumatoid Arthritis;	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Rheumatoid Factor Positive; Seronegative	Sulfasalazine	S	Oral		Not Reported
Arthritis; Sleep Disorder;	Sulfasalazine	S	Oral		Not Reported
Swelling; Synovitis;	Sulfasalazine	S	Oral		Not Reported
Systemic Lupus	Sulfasalazine	S	Oral		Not Reported
Erythematousus;	Sulfasalazine	S	Subcutaneous		Not Reported
Therapeutic Product Effect	Cortisone	S	Topical		Not Reported
Decreased; Treatment	Cortisone	S	Oral		Not Reported
Failure; Treatment	Cortisone Acetate	S	Oral		Not Reported
Noncompliance; Type 2	Cortisone Acetate	S	Topical		Not Reported
Diabetes Mellitus; Walking					
Aid User; Weight					
Decreased; Wound;					
Wound Infection					

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Cortisone Acetate	S	Oral	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Desoximetasone	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Topicort (Hydrocortisone Acetate)	S	Cutaneous	Not Reported
Topicort (Hydrocortisone Acetate)	S	Oral	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Acetaminophen	S	Oral	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported

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Methotrexate Sodium	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Cosentyx	S		Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	12912114	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20160308952			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Conjunctivitis; Fatigue; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Infection	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Amlodipine Besilate			C				Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported
	Lyrica			C	Oral			Not Reported
	Mavik			C	Unknown			Not Reported
	Olopatadine Hydrochloride			C	Ophthalmic			Not Reported

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Prednisone			C		Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	12914315	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-093127		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Amino	Orencia			S	Intravenous (not otherwise specified)	760 Milligram, Qwk		Bristol Myers Squibb	
Increased; Alopecia; Arthralgia; Aspartate Amino	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb	
Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb	
Decreased; C-Reactive Protein Abnormal; C-Reactive Protein	Tocilizumab			S	Unknown	360 Milligram, Q4wk		Not Reported	
Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance	Tocilizumab			S	Unknown	680 Milligram, Q4wk		Not Reported	
Decreased; Enthesopathy; Erythema; Gastric Disorder; Granuloma Skin; Headache;	Tocilizumab			S	Unknown	360 Milligram, Qwk		Not Reported	
Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Tocilizumab			S	Unknown	360 Milligram		Not Reported	
Musculoskeletal Disorder; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling;	Tocilizumab			S	Unknown	680 Milligram		Not Reported	
	Rituximab			S	Unknown	380 Milligram		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Qd		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported	
	Rituximab			S	Unknown	1000 Milligram, Bid		Not Reported	
	Methotrexate			S	Subcutaneous	10 Milligram, Q2wk		Not Reported	
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported	
	Methotrexate			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported	
	Methotrexate			S	Subcutaneous	70 Milligram, Qwk		Not Reported	
	Methotrexate			S	Subcutaneous	12.5 Milligram, Qwk		Not Reported	
	Methotrexate			S	Subcutaneous	12 Milligram, Qwk		Not Reported	
	Methotrexate			S	Unknown	12 Milligram, Qwk		Not Reported	
	Methotrexate			S	Unknown	12.5 Milligram, Qwk		Not Reported	
	Methotrexate			S	Unknown	10 Milligram, Qwk		Not Reported	

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Product Use Issue;	Methotrexate	S	Unknown	12.5 Milligram, Q4wk	Not Reported
Psoriatic Arthropathy;	Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
Rash; Rash Pruritic; Red	Methotrexate	S	Unknown	15 Milligram, Q4wk	Not Reported
Blood Cell Sedimentation	Methotrexate	S	Unknown	17.5 Milligram, Q4wk	Not Reported
Rate Increased;	Methotrexate	S	Unknown	70 Milligram, Q2wk	Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Subcutaneous	10 Milligram, Q2wk	Not Reported
Rheumatoid Nodule; Skin	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
Necrosis; Skin Ulcer;	Methotrexate	S	Subcutaneous	10 Milligram, Q4wk	Not Reported
Synovitis; Tendonitis;	Methotrexate	S	Oral	20 Milligram	Not Reported
Tenosynovitis;	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
Therapeutic Product Effect	Methotrexate	S	Unknown	10 Milligram, Q4wk	Not Reported
Decreased; Therapeutic	Methotrexate	S	Oral	20 Milligram	Not Reported
Product Effect Incomplete;	Methotrexate	S	Unknown	20 Milligram	Not Reported
Therapeutic Response	Leflunomide	S	Oral	40 Milligram, Q2wk	Not Reported
Decreased; Tongue	Leflunomide	S	Oral	20 Milligram	Not Reported
Disorder; Ulcer	Leflunomide	S	Subcutaneous	20 Milligram	Not Reported
	Adalimumab	S	Oral	380 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	25 Milligram, Q2wk	Not Reported
	Enbrel	S	Unknown	25 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	360 Milligram, Qmo	Not Reported
	Hydroxychloroquine	S	Unknown	680 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	Unk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported

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

Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Unknown	10 Milligram	Not Reported
Myochrysine	S	Unknown	50 Milligram, Qmo	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Q4wk	Not Reported
Alendronate Sodium	S	Unknown	70 Milligram, Qwk	Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Rituxan	S	Unknown	1000 Milligram, Bid	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Cyclosporin	C	Unknown	Unk	Not Reported
Cyclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Actemra	S	Unknown	680 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	360 Milligram, Q4wk	Not Reported
Actemra	S	Unknown	2.68 Milligram, Q4wk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	680 Milligram, Qmo	Not Reported
Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Apo-Ibuprofen	S	Oral	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
Apremilast	S	Unknown		Not Reported
Apremilast	S	Unknown		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported

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Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ibuprofen	S	Oral	600 Milligram, Qd	Not Reported
Infliximab	S	Oral	Unk	Not Reported
Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Colchicine	C	Unknown	Unk	Not Reported
Dexilant	C	Oral	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Milligram, Bid	Not Reported
Prednisolone	C	Unknown	10 Milligram	Not Reported
Prednisolone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Alendronate	C	Unknown	70 Milligram, Qwk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Etanercept	S	Unknown	25 Milligram, Q2wk	Not Reported
Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	13068783	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161203380			Male	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Intolerance; Headache; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Tremor	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Enbrel			S	Subcutaneous	Duration Is 9 Months		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical For -244.0		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Morphine /00036302/ Naprosyn /00256201/ Zopiclone			S S C	Topical Unknown	1.0 Dosage Form		Not Reported Not Reported
	Folic Acid			C	Oral			Not Reported
	Pantoprazole Magnesium			C	Oral			Not Reported
	Tenofovir Disoproxil Fumarate			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	13319448	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902949			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Contraindicated	Rituxan			S	Intravenous (not			Not Reported

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

Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Enbrel	S	otherwise specified)			Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine	S	Unknown			Not Reported
	Leflunomide	S	Unknown			Not Reported
	Methotrexate Sodium	S	Unknown			Not Reported
	Orencia	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Powder For Suspension		Not Reported
	Desoximetasone	C	Oral			Not Reported
	Diclofenac	C	Unknown			Not Reported
	Xeljanz	C	Oral			Not Reported
	Cortisone	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	14908110	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP013244			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Meloxicam			S	Oral	7.5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
	Mobicox			S	Oral	7.5 Mg, Qd		Not Reported
	Actemra			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

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

Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Sulfasalazine	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	14999486	EXPEDITED (15-DAY)		DE, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-175486		67 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Death; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Lorazepam			S	Unknown	Unk ()		Sun
	Montelukast			S	Unknown	Unk ()		Not Reported
	Celecoxib			S	Unknown	Unk ()		Not Reported
	Warfarin			S	Unknown	Regimen 1 ()		Not Reported
	Influenza Vaccine Inactivated			S	Unknown	Unk ()		Not Reported
	Asa			S	Endocervical	Unk ()		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk ()		Not Reported
	Hydroxychloroquine			S	Unknown	Unk ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15268901	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168136			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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

Minocycline	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Clavulanate Potassium	C		Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15360741	EXPEDITED (15-DAY)	CA, DE, DS, OT		DE-TORRENT-00009759			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Acetylsalicylic Acid			S	Transplacental	From Gestational Week 0-14		Unknown
	Aliskiren			S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week		Unknown
	Clexane			S	Transplacental	Exposure Duration: 0-14 Weeks		Unknown
	Dalteparin Sodium			S	Transplacental	Unknown		Unknown
	Enoxaparin Sodium			S	Transplacental	From Gestational Week 0-14		Unknown
	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Unknown
	Heparin			S	Transplacental	Unknown		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Unknown
	Metamizole			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Unknown
	Pantoprazole			S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week		Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Unknown
	Ramipril			S	Transplacental	20 Mg Per Day, Exposure		Not Reported

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

Rituximab	S	Transplacental	Duration: 0-113+6 Weeks / Maternal Dose 20 Mg, Unknown	Unknown
Salbutamol	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Unknown
Simvastatin	S	Transplacental	From Gestational Week 0- 14	Not Reported
Tacrolimus	S	Transplacental	From Gestational Week 0- 14	Unknown
Torsemide	S	Transplacental	From Gestational Week 0- 14	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0- 5	Unknown
Cytotec	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
Mifegyne	C	Transplacental	Unk; 13.6 Gestational Week	Unknown
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15623907	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2554647-00		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Contraindicated Product	Humira			S	Subcutaneous			Not Reported
Administered; Drug	Actemra			S	Unknown			Not Reported
Ineffective; Drug	Apo-Leflunomide			S	Unknown			Not Reported
Intolerance; Fatigue;	Plaquenil			S	Unknown			Not Reported
Helicobacter Infection; Hot Flush; Hypertension; Joint	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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

Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Calcium Carbonate	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Elavil	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Premarin	C	Unknown	Not Reported
	Tenormin	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Sumatriptan Succinate	C	Unknown	Not Reported
	Imitrex	C	Unknown	Not Reported
	Sumatriptan	C	Unknown	Not Reported
	Amitriptyline	C		Not Reported
	Tofacitinib	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15624422	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2556711-00		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Abdominal Pain Upper; Arthropathy; Condition Aggravated;	Humira	S	Subcutaneous	Not Reported
Contraindicated Product Administered; Deformity; Diarrhoea; Disease Progression; Drug Ineffective; Drug	Anakinra	S	Unknown	Not Reported
Interaction; Embolism; Fear; Fine Motor Skill Dysfunction; Finger Deformity; Hand Deformity; Impaired Healing; Musculoskeletal Disorder; Nausea; Off Label Use; Pain; Rash;	Apo-Warfarin	S	Unknown	Not Reported
Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Celebrex	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Warfarin	S	Unknown	Not Reported
	Methotrexate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15629635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028- 2557205-00		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; General Physical Health Deterioration; Knee Arthroplasty; Rheumatoid Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

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

	Plaquenil		S	Unknown				Not Reported	
	Plaquenil		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15668157	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2570296-00		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Humira			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Arthrotec			S	Unknown			Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
	Ceclor			S	Unknown			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Demerol			S	Unknown			Not Reported	
	Erythro Base			S	Unknown			Not Reported	
	Erythromycin Estolate			S	Unknown			Not Reported	
	Levofloxacin Hemihydrate			S	Unknown			Not Reported	
	Lyrica			S	Unknown			Not Reported	
	Meperidine Hydrochloride			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Metronidazole			S	Intravenous (not otherwise specified)	Dosage Form-Liquid Intravenous		Not Reported	
	Norfloxacin			S	Unknown			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Erythromycin			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	

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

Bisoprolol Fumarate	S	Unknown	Not Reported
Celecoxib	S	Oral	Not Reported
Meperidine	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Cefaclor	S	Unknown	Not Reported
Leflunomide Sandoz	S	Unknown	Not Reported
Noritate	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Act Diclo Miso	S	Unknown	Enteric Coated
Diclofenac + Misoprostol	S	Unknown	Not Reported
Aurovitas			
Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15676976	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2573583-00		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Actonel	S	Unknown	Not Reported
	Apo Risedronate	S	Unknown	Not Reported
	Apo Risedronate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Risedronate	S	Unknown	Not Reported
	Apo Risedronate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	C		Not Reported
	Hydroxychloroquine Sulfate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	15713218	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS- 2018GMK038625			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphopenia	Tacrolimus			S	Transplacental	Unk		Glenmark
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	16080823	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-013796		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; No Adverse Event	Celecoxib Capsules			S	Oral	Unk		Aurobindo
	Celecoxib			S	Unknown	Unk		Aurobindo

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

Celecoxib	S			Aurobindo
Actemra	S	Unknown	Unk	Not Reported
Anakinra	S	Unknown	100 Milligram	Not Reported
Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Apo-Prednisone	S	Unknown	7 Milligram, Once A Day	Not Reported
Celebrex	S	Oral	Unk	Not Reported
Celebrex	S			Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	1 Milliliter, Every Week	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Celebrex	S	Unknown	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Humira	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	16639635	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2867070-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint	Humira			S	Subcutaneous			Not Reported
	Sulfasalazin			S	Oral			Not Reported

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

Swelling; Musculoskeletal Stiffness; Treatment Failure	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Etanercept	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17531498	EXPEDITED (15-DAY)		DS, HO, OT	CA-GLAXOSMITHKLINE-CA2020044221		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contusion; Grip Strength Decreased; Joint Swelling; Osteoarthritis; Rheumatoid Arthritis; Spinal Stenosis; Tenderness; Treatment Failure	Diclofenac			S	Oral	1 Df		Glaxosmithkline
	Diclofenac			S	Oral	2 Df, Qd		Glaxosmithkline
	Diclofenac			S	Oral	75 Mg, Bid		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac			S	Oral	Unk, Qd		Glaxosmithkline
	Diclofenac			S	Oral	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Oral	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Pantoprazole			S	Unknown	Unk		Glaxosmithkline
	Voltaren Sr			S	Oral	2 Df, Qd (75 Mg)		Glaxosmithkline
	Voltaren Sr			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	Unk		Glaxosmithkline
	Cambia			S	Oral	Unk, Qd		Glaxosmithkline
	Cambia			S	Oral	Unk		Glaxosmithkline
	Cambia			S	Unknown	75 Mg, Bid		Glaxosmithkline
	Lisinopril			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported

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

Sulfasalazine	S	Oral	2 Df, Qd (1 Gram)	Not Reported
Sulfasalazine	S	Unknown	1 Df, Qd (500 Mg)	Not Reported
Plaquenil	S	Oral	1 Df, Qd	Not Reported
Synthroid	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Gold	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17685737	EXPEDITED (15-DAY)	DE		IE-JNJFOC-20200410813		57 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Mabthera			S				Not Reported
	Humira			S				Not Reported
	Protium			C	Unknown			Not Reported
	Agomelatine			C	Unknown			Not Reported
	Alendronate (Generic)			C	Unknown			Not Reported
	Levothyroxine Sodium (G)			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Prednisolone (Generic)			C	Unknown			Not Reported
	Depo-Medrone			C	Unknown			Not Reported
	Sodium Aurothiomalate (G)			C	Unknown			Not Reported
	Methotrexate (G)			C	Unknown			Not Reported
	Sulfasalazine (G)			C	Unknown			Not Reported
	Seroquel			C				Not Reported
	Agomelatine			C				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690789	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584439			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690794	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226002		73 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	200 Milligram Daily; 200 Mg/24h		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; 600mg/24h		Not Reported

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Tocilizumab (8289a)	S							Not Reported
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h					Not Reported
Ceftriaxona (501a)	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690857	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032312		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Arthralgia; Aspartate	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein	Alendronate Sodium			S	Unknown	70 Milligram, Qwk		Not Reported	
Increased; Dermatitis; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Neoplasm Skin; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Incomplete;	Apo-Lefflunomide			S	Unknown	Unk		Not Reported	
	Codeine			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	25 Milligram		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Oral	10 Milligram, Qwk		Not Reported	
	Methotrexate			S	Subcutaneous	Unk Unk, Qwk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram, Bid		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Tocilizumab			S	Unknown	680 Milligram		Not Reported	
	Ciclosporin			C	Unknown	150 Milligram, Qd		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Rituxan			C	Unknown	Unk		Not Reported	
	Xeljanz			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ulcer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690973	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB- 001159			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Drug Intolerance; Gastrointestinal Disorder; Headache; Nausea; Urinary Tract Infection	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	20 Milligram, Qd		Not Reported
	Prednisolone			S	Unknown	9 Milligram, Qd		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Amoxicillin			S				Not Reported
	Co-Amoxiclav			S	Unknown	Unk		Not Reported
	Gentamycin			S	Unknown	Unk		Not Reported
	Tobramycin			S	Unknown	Unk		Not Reported
	Colomycin [Colistimethate Sodium]			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Tazobactam/Piperallin			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Cefradine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584770			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea;	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported

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

Treatment Failure; Vomiting	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691161	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101231			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Arava			S		20 Mg		Sanofi
	Arava			S		Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Leflunomide			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	7.5 Mg		Not Reported
	Methotrexate			S	Subcutaneous	20.0 Mg		Not Reported
	Actemra			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

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Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
Diclofenac Sodium And Misoprostol	S		50 Mg, Bid	Not Reported
Arthrotec	C		50 Mg, Bid	Not Reported
Gold	C			Not Reported
Imuran [Azathioprine]	C			Not Reported
Vitamin D3	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691162	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA100870		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Leflunomide			S	Oral	10 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Cefazolin			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Viread			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691425	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225669		33 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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Hepatitis	Hidroxiclороquina (2143a)	S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400mg	Teva
	Hidroxiclороquina (2143a)	S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400 Mg	Teva
	Azitromicina (7019a)	S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Does 500 Mg	Not Reported
	Azitromicina (7019a)	S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Dose 250 Mg	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2gr/24h, Unit Dose 2 Gm	Not Reported
	Ceftriaxona (501a)	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691428	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA104277		80 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Ceftriaxone			S				Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691526	EXPEDITED (15-DAY)		HO, LT	SI-ABBVIE-20K-261-3372991-00		48 YR	Male	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Immune Thrombocytopenia; Thrombocytopenia	Kaletra			S	Oral	(80mg+20mg)/MI Oral Solution, Dose 400mg/100		Not Reported

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

					Mg				
	Hydroxychloroquine Sulfate	S	Oral						Not Reported
	Piperacillin/Tazobactam	C							Not Reported
	Esmeron	C							Not Reported
	Metoclopramid	C							Not Reported
	Analgin	C							Not Reported
	Pantoprazole	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691529	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202003003107			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thyroid Cancer	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691630	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101016			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
Alopecia; Arthralgia;	Celecoxib			S	Unknown			Not Reported
Diarrhoea; Drug	Leflunomide			S	Unknown			Sanofi
Ineffective; Joint Stiffness;	Methotrexate			S	Unknown			Not Reported
Liver Function Test	Sulfasalazine			S	Unknown			Not Reported
Abnormal; Mobility	Orencia			S	Unknown			Not Reported
Decreased; Pneumonia;	Actemra			S	Unknown			Not Reported
Swelling; Therapeutic	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Product Effect Decreased;	Enbrel			S	Unknown			Not Reported
Treatment Failure;	Bifidobacterium Bifidum			C	Unknown			Not Reported
Vomiting	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown	Unk Unk, Tid		Not Reported

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Xeljanz			C	Oral	5 Mg, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584596			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accident; Alopecia;	Actemra			S	Unknown			Not Reported	
Bronchitis Chronic; Drug	Rituxan			S	Intravenous drip			Not Reported	
Hypersensitivity; Drug	Enbrel			S	Unknown			Not Reported	
Ineffective; Drug	Humira			S	Subcutaneous			Not Reported	
Intolerance; Neck Pain;	Methotrexate			S	Unknown			Not Reported	
Off Label Use;	Orencia			S	Unknown			Not Reported	
Rheumatoid Factor	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
Positive; Spinal Column	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
Injury; Synovitis	Arava			S	Oral			Not Reported	
	Mobicox			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691915	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584504			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction;	Rituxan			S	Intravenous drip			Not Reported	
Blood Cholesterol	Arava			S	Unknown			Not Reported	
Increased; C-Reactive	Azathioprine			S	Unknown			Not Reported	
Protein Abnormal; Drug	Enbrel			S	Subcutaneous			Not Reported	
Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported	
Ineffective; Drug	Hydroxychloroquine			S	Unknown			Not Reported	
Intolerance; Rash; Red	Methotrexate			S	Subcutaneous			Not Reported	
Blood Cell Sedimentation									
Rate Abnormal; Synovitis									

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	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17692044	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101011		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Prednisone			S	Oral	20 Mg		Not Reported
	Myocrisin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown	50 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Bid		Not Reported
	Rituxan			S	Unknown	1 G, Bid		Not Reported

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Simponi	S	Unknown	50 Mg	Not Reported
Apo Prednison	S	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17692427	EXPEDITED (15-DAY)		OT	CN-ADVANSZ PHARMA-202004003310			Unknown	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Coronavirus Infection; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17692563	EXPEDITED (15-DAY)		DE, OT	FR-ADVANSZ PHARMA-202004003424			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Organ Dysfunction Syndrome; Off Label Use; Overdose; Pneumonia Bacterial; Septic Shock	Hydroxychloroquine			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		200 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Cefepim Amomed			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Atracurium Besilate			C		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17692890	NON-EXPEDITED			US-AMGEN-USASP2020063491		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Eye Disorder; Injection Site Pain; Pain; Sinusitis	Enbrel			S	Unknown	Unk		Amgen	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17692900	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003924		95 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
	Quetiapine			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Risperidone			S	Oral			Not Reported	
	Ritonavir/Lopinavir			S	Oral			Not Reported	
	Losartan			C	Oral			Not Reported	
	Clindamycin Hydrochloride			C	Intravenous (not otherwise specified)			Not Reported	
	Lorazepam			C	Oral			Not Reported	
	Furosemide			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17692945	EXPEDITED (15-DAY)		OT	CN-ADVANSZ PHARMA-202004003226			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Liver Injury; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	

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22-Apr-2020	17693787	EXPEDITED (15-DAY)		DE, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032939		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Doxycycline Hyclate			S	Unknown	50 Milligram		Not Reported	
	Enbrel			S	Unknown	Unk, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Humira			S	Unknown	40 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported	
	Leflunomide			S	Unknown	10 Milligram, Qd		Not Reported	
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported	
	Remicade			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Rituximab;Urelumab			C	Unknown			Not Reported	
	Simponi			C	Unknown	Unk		Not Reported	
	Xeljanz			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17693828	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 13401			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Iron Abnormal; Disease Progression; Drug Ineffective; Drug Intolerance; Product Use Issue; Rheumatoid Arthritis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown	Unknown		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown	Unknown		Not Reported	
	Azathioprine			S	Unknown	Unknown		Not Reported	
	Ciclosporin			S	Unknown	Unknown		Not Reported	
	Cimzia			S	Subcutaneous	Single-Use Pre Filled Syringe, Solution Subcutaneous		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unknown		Not Reported	
	Methotrexate			S	Unknown	Unknown		Not Reported	
	Sulfasalazine			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17693966	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200419466		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral	Simponi			S	Subcutaneous			Janssen	
	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	

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Infection	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17694029	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225643		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva	
	Hidroxicloroquina (2143a)			S	Oral	1er Día 400 Mg/12 H, A Partir Del 2º Día 400mg/24 H		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg 1st Dose, Later 250mg / 24h		Not Reported	
	Azitromicina (7019a)			S	Oral			Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; Single Dose		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17694856	EXPEDITED (15-DAY)		LT	FR-ELI_LILLY_AND_COMP ANY-FR202004008033		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg, Daily		Eli Lilly And Co	
	Plaquenil Sulfate			S	Oral	800 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17695215	EXPEDITED (15-DAY)		DE	IT-AUROBINDO-AUR-APL-2020-019985		70 YR	Male	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17695429	EXPEDITED (15-DAY)		HO	DE-BAXTER-2020BAX008027		31 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epidermal Necrosis;	Endoxan Lyophilisat			S	Unknown			Baxter	
Epidermal Necrosis; Lip Disorder; Lip Disorder;	Leflunomide			S	Unknown			Not Reported	
Pigmentation Disorder;	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported	
Skin Lesion; Skin Lesion;	Chloroquine			S	Unknown			Not Reported	
Stevens-Johnson Syndrome; Toxic	Prednisone			S	Unknown			Not Reported	
Epidermal Necrolysis;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Toxic Epidermal Necrolysis; Toxic	Prednisolone			S	Nasal			Not Reported	
Epidermal Necrolysis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	12764963	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-076342		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported	
	Naproxen			S	Unknown			Not Reported	

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

Malaise; Multiple	Apo-Leflunomide	S	Oral	5 Milligram, Bid	Not Reported
Fractures; Osteoporosis;	Apo-Prednisone	S	Unknown	Unk	Not Reported
Osteoporotic Fracture;	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Pain; Rash; Red Blood	Xeljanz	S	Unknown	12.5 Milligram	Not Reported
Cell Sedimentation Rate	Xeljanz	S	Oral	50 Milligram, 2 Every 1	Not Reported
Abnormal; Synovitis				Day	
	Prednisone	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Aleve	S	Unknown		Not Reported
	Methotrexate	S	Unknown	20 Milligram	Not Reported
	Cosentyx	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Prednisone Teva	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Apo-Naproxen	S	Unknown	Unk	Not Reported
	Naproxen Sodium	S	Oral	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	400 Milligram	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
	Insulin	C	Unknown	Unk	Not Reported
	Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
	Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	13665971	EXPEDITED (15-DAY)		OT	TN-BAUSCH-BL-2017-019520		33 YR	Female	TUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Prednisolone			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Chloroquine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	13974821	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018007			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported	
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex	
	Prednisone			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Cortisone Acetate			S	Topical	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituxan			S	Intravenous (not	Unk		Not Reported	

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

Prednisone S otherwise specified) Intravenous (not otherwise specified) Unk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	14235430	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX-2017AP021569		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased;	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Hydroxyquine			S	Oral	Unk		Apotex
	Apo-Alendronate			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Oral	500 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.I.W		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Ibuprofen			S	Oral	Unk		Apotex
	Ibuprofen			S	Oral	600 Mg, Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Codeine			S	Unknown	Unk		Not Reported
	Apremilast			S	Unknown	60 Mg, Bid		Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Otezla			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Infliximab			S	Oral	Unk		Not Reported
	Motrin			S	Oral	600 Mg, Qd		Not Reported
	Motrin			S	Oral	Unk Unk, Qd		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

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

Rheumatoid Arthritis;	Stelara	S	Subcutaneous	Unk	Not Reported
Rheumatoid Nodule; Skin	Enbrel	S	Unknown	25 Mg, Two Every One	Not Reported
Necrosis; Skin Ulcer;				Week	
Synovitis; Tendonitis;	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
Tenosynovitis;	Enbrel	S	Subcutaneous	Unk	Not Reported
Therapeutic Response	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
Decreased; Tongue	Enbrel	S	Subcutaneous	40 Mg, Unk	Not Reported
Disorder; Ulcer	Humira	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	17.5 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	12 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	10 Mg, Q.I.W	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, Q.I.W	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Unknown	70 Mg, Q.Wk.	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported

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

Rituxan	S	Intravenous (not otherwise specified)	11000 Mg, Q.12h	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	360 Mg, One Every Month	Not Reported
Tocilizumab	S	Unknown	680 Mg, One Every Four Week	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	380 Mg, Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	20 Mg, Unk	Not Reported
Xeljanz	C	Unknown		Not Reported
Humira	C	Unknown	40 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	10 Mg, Unk	Not Reported
Methotrexate	C	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	C	Unknown	12 Mg, Q.Wk.	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	C	Unknown	680 Mg, Unk	Not Reported
Tocilizumab	C	Unknown	360 Mg, Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Mg, Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Unk	Not Reported

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

Alendronate	C	Unknown	70 Mg, Q.Wk.	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Mg, Unk	Not Reported
Benadryl /00000402/	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	14497211	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-027214			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Adverse Event; Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Tofacitinib Citrate			S	Oral	5 Milligram, Bid		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported

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

Methotrexate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown	Unk	Not Reported
Hydromorphone	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	14921412	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-044420		63 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	2.0 Dosage Form, Qd		Not Reported
	Hydroxychloroquine			S	Oral	10.0 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	5.0 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Endocervical	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Oral	Unk		Not Reported

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

Cyclosporine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Subcutaneous	20 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Oral	2 Dosage Form, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Bid	Not Reported
Hydroxychloroquine Sulfate	S	Oral	10 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	Unk	Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Milligram	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	2 Ot, Qd	Not Reported
Xeljanz	C	Oral	10 Milligram, Qd	Not Reported
Xeljanz	C	Oral	5 Milligram, Qd	Not Reported
Xeljanz Xr	C	Unknown	Unk	Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	16731204	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2019152774		78 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline	
Abdominal Pain Upper;	Voltaren(Diclofenac)			S	Unknown	Unk		Glaxosmithkline	
Arthropathy; Deafness;	Voltaren(Diclofenac)			S				Glaxosmithkline	
Deafness Transitory;	Voltaren(Diclofenac)			S				Glaxosmithkline	
Decreased Appetite;	Voltaren(Diclofenac)			S				Glaxosmithkline	
Dizziness; Drug	Vitamin C			S	Unknown	Unk		Glaxosmithkline	
Hypersensitivity; Ear	Motrin			S	Unknown	Unk		Glaxosmithkline	
Infection; Eating Disorder;	Motrin			S				Glaxosmithkline	
Feeding Disorder;	Motrin			S				Glaxosmithkline	
Functional Gastrointestinal	Motrin			S				Glaxosmithkline	
Disorder; Gastrointestinal	Aspirin			S	Unknown	Unk		Glaxosmithkline	
Disorder; Gastrointestinal	Aspirin			S				Glaxosmithkline	
Pain; Headache;	Aspirin			S				Glaxosmithkline	
Hypophagia;	Aspirin			S				Glaxosmithkline	
Musculoskeletal Disorder;	Aspirin			S				Glaxosmithkline	
Nausea; Off Label Use;	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline	
Pharyngitis; Vomiting;	Clopidogrel			S	Unknown	Unk		Glaxosmithkline	
Weight Decreased	Clopidogrel			S				Glaxosmithkline	
	Clopidogrel			S				Glaxosmithkline	
	Clopidogrel			S				Glaxosmithkline	
	Clopidogrel			S				Glaxosmithkline	
	Ibuprofen			S	Unknown	Unk		Glaxosmithkline	
	Sulfamethoxazole			S	Unknown	Unk		Glaxosmithkline	
	Arava			S	Oral	Unk		Not Reported	
	Arava			S				Not Reported	
	Arava			S				Not Reported	
	Arava			S				Not Reported	
	Asa			S	Unknown	325 Mg (Delayed Release)		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S				Not Reported	
	Methotrexate			S				Not Reported	
	Methotrexate			S				Not Reported	

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

Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Humira	S			Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Plaquenil	S			Not Reported
Apo-Diclofenac	S	Topical	Unk	Not Reported
Naproxen	S	Unknown	Unk	Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Naproxen	S			Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Unk	Not Reported
Tramadol	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Gold	S			Not Reported
Gold	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	16748699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2381845		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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

Methotrexate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17004240	EXPEDITED (15-DAY)	DS, OT		CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-103496		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aleve			C	Unknown	Unk		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

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

Simponi	C	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17035098	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1136345		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Prednisone			S	Oral	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported
	Simponi			S	Subcutaneous			Not Reported
Sulfasalazine			S	Unknown			Not Reported	
Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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

Rituxan	S	Intravenous (not otherwise specified)	2000 Milligram Daily;	Not Reported
Rituxan	S	Unknown	2 Gram Daily;	Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram Daily;	Not Reported
Xeljanz	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17040026	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3002083-00		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported
Adverse Event; Alopecia;	Actemra			S	Subcutaneous			Not Reported
Anti-Cyclic Citrullinated	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Peptide Antibody Positive;	Pseudoephedrine Hcl			S	Unknown			Not Reported
Arthropathy; Condition	Phthalylsulfathiazole			S	Unknown			Not Reported
Aggravated;	Orencia			S	Subcutaneous			Not Reported
Contraindicated Product	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Administered; Discomfort;	Methotrexate Sodium			S	Unknown			Not Reported
Drug Ineffective; Drug	Fosamax			S	Oral			Not Reported
Intolerance; Duodenal	Enbrel			S	Subcutaneous			Not Reported
Ulcer Perforation; Fatigue;	Cortisone Acetate			S	Topical			Not Reported
Glossodynia; Hand	Cortisone Acetate			S	Unknown			Not Reported
Deformity; Hepatic	Cimzia			S	Subcutaneous	Solution Use Single-Use Pre-Filled Syringe		Not Reported
Enzyme Increased; Hip	Cimzia			S	Subcutaneous			Not Reported
Arthroplasty; Infusion	Cetirizine Hydrochloride			S	Unknown			Not Reported
Related Reaction; Joint	Apo-Prednisone			S	Unknown			Not Reported
Swelling; Knee	Apo-Hydroxyquine			S	Unknown			Not Reported
Arthroplasty; Live Birth;	Folic Acid			S	Unknown			Not Reported
Maternal Exposure During								
Pregnancy; Off Label Use;								
Pain; Pemphigus;								
Pericarditis; Product Use								
Issue; Rash; Rheumatoid								
Arthritis; Rheumatoid								
Factor Positive; Swelling;								
Synovitis; Systemic Lupus								
Erythematousus; Wound								

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

Folic Acid	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Arava	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Not Reported
Topicort [Hydrocortisone Acetate]	S	Topical	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Diclofenac	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Arava	S	Intravenous (not Powder For Solution For	Not Reported

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

		otherwise specified)	Infusion	
Etanercept	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Sarilumab	S	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Atasol	C			Not Reported
Salazopyrin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17191010	EXPEDITED (15-DAY)		OT	NVSC2019CA076411			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown	Unk		Novartis
Alopecia; Arthropathy;	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Contraindicated Product	Methotrexate Sodium			S	Unknown	Unk		Not Reported
Administered; Discomfort;	Etanercept			S	Subcutaneous	Unk		Not Reported
Drug Ineffective; Fatigue;	Folic Acid			S	Unknown	1 Mg		Not Reported
Glossodynia; Hand	Folic Acid			S	Unknown	5 Mg		Not Reported
Deformity; Maternal	Adalimumab			S	Subcutaneous	40 Mg Solution		Not Reported
Exposure During	Desoximetason			S	Oral	Unk		Not Reported
Pregnancy; Off Label Use;	Fosamax			S	Oral	Unk		Not Reported
Pain; Pemphigus; Product	Methotrexate			S	Oral	Unk		Not Reported
Use Issue; Rash;	Methotrexate			S	Intra-arterial	Unk		Not Reported
Rheumatoid Arthritis;	Cimzia			S	Subcutaneous	Unk		Not Reported
Swelling; Systemic Lupus	Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported
Erythematous; Wound	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

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

Tocilizumab	S	Subcutaneous	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Subcutaneous	500 Mg	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17350586	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-004765			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb	
	Actemra			S	Unknown	8 Milligram		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	
	Methotrexate			S	Unknown	20 Milligram, Qd		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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

Leflunomide	S	Unknown	20 Milligram	Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Milligram	Not Reported
Meloxicam	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17554482	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022709		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Orencia			S	Intravenous (not	250 Milligram, Qmo		Bristol Myers Squibb
Arthritis; Arthropathy;					otherwise specified)			
Body Height Below	Orencia			S	Intravenous (not	250 Milligram		Bristol Myers Squibb
Normal; Bone Density					otherwise specified)			
Decreased; C-Reactive	Orencia			S	Intravenous (not	200 Milligram, Qmo		Bristol Myers Squibb
Protein Increased;					otherwise specified)			
Condition Aggravated;	Actemra			S	Intravenous (not	280 Milligram		Not Reported
Diarrhoea; Dizziness;					otherwise specified)			
Drug Ineffective; Drug	Actemra			S	Intravenous (not	280 Milligram, Qwk		Not Reported
Intolerance; Drug Specific					otherwise specified)			
Antibody Present;	Actemra			S	Intravenous (not	280 Milligram, Q2wk		Not Reported
Gastroenteritis Viral;					otherwise specified)			
Human Anti-Human	Adalimumab			S	Unknown			Not Reported
Antibody Test; Human	Adalimumab			S	Subcutaneous			Not Reported
Antichimeric Antibody	Anakinra			S	Subcutaneous			Not Reported
Positive; Hypocalcaemia;								
Hypokalaemia;	Anakinra			S	Subcutaneous	50 Milligram, Qwk		Not Reported
Hypotension;								
Immunodeficiency;	Anakinra			S	Unknown	50 Milligram		Not Reported
Impaired Quality Of Life;								
Joint Destruction; Joint	Anakinra			S	Subcutaneous	50 Milligram, Qd		Not Reported
Effusion; Joint Injury;								
Juvenile Idiopathic	Apo-Naproxen			S	Unknown			Not Reported
Arthritis; Liver Function								
Test Abnormal; Loss Of	Apo-Naproxen			S	Unknown			Not Reported
Consciousness; Loss Of								
Personal Independence In	Apo-Prednisone			S	Oral	3 Milligram, Bid		Not Reported
Daily Activities; Mobility								
Decreased; Nausea;	Apo-Prednisone			S	Oral	1.3 Milligram, Bid		Not Reported

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

Obesity; Off Label Use;	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
Pleural Effusion;	Apo-Prednisone	S	Oral	50 Milligram	Not Reported
Polyarthritis; Prescribed	Enbrel	S	Subcutaneous	25 Milligram	Not Reported
Underdose; Psoriasis;	Enbrel	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
Pyrexia; Red Blood Cell	Humira	S	Subcutaneous		Not Reported
Sedimentation Rate	Hydroxychloroquine	S	Oral	Unk	Not Reported
Increased; Rheumatoid	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
Arthritis; Septic Shock;	Immune Globulin	S	Intravenous (not		Not Reported
Synovitis; Therapeutic	(Immunoglobulins Nos)		otherwise specified)		
Product Effect Decreased;	Immune Globulin	S	Intravenous (not	70 Gram	Not Reported
Therapy Non-Responder;	(Immunoglobulins Nos)		otherwise specified)		
Vomiting	Infliximab	S	Intravenous (not	3 Milligram/Kilogram	Not Reported
			otherwise specified)		
	Infliximab	S	Intravenous (not	3 Milligram/Kilogram,	Not Reported
			otherwise specified)	Q6wk	
	Infliximab	S	Intravenous (not	5 Milligram	Not Reported
			otherwise specified)		
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram/Sq. Meter,	Not Reported
				Qwk	
	Methotrexate	S	Unknown	15 Milligram/Sq. Meter,	Not Reported
				Q2wk	
	Naproxen	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	50 Milligram, Bid	Not Reported
	Prednisone	S	Unknown	50 Milligram	Not Reported
	Prednisone	S	Oral	1.3 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported

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

Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram	Not Reported
Tocilizumab	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Triamcinolone Hexacetonide	S	Other		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
Folic Acid	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17566294	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200321035			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported

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

Actemra	S	Unknown	Not Reported
Imuran /00001501/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17566419	EXPEDITED (15-DAY)	OT		CA-JNJFOC-20200318563		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Irritable Bowel Syndrome; Off Label Use; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Infliximab, Recombinant			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Bimatoprost			C	Ophthalmic			Not Reported
	Nexium /01479302/			C	Unknown			Not Reported
	Suphedrine /00005601/			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol /00020001/			C	Unknown			Not Reported
	Tylenol /00020001/			C				Not Reported
	Valsartan			C	Unknown			Not Reported
Wellbutrin			C	Unknown			Not Reported	
Acetaminophen			C	Unknown			Not Reported	

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

Esomeprazole Sodium	C	Unknown	Not Reported
Lumigan Rc	C	Ophthalmic	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17605662	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332777		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Increased; Cataract; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Sulfasalazine			S	Unknown			Not Reported	
Xeljanz			S	Oral			Not Reported	
Xeljanz			S	Oral			Not Reported	

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

Arava	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Acetaminophen	C		Not Reported
Altace	C	Unknown	Not Reported
Asa	C		Not Reported
Codeine	C		Not Reported
D-Alpha Tocopherol	C		Not Reported
Ergocalciferol	C		Not Reported
Folic Acid	C		Not Reported
Rosuvastatin Calcium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17606950	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318841		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Simponi			S	Subcutaneous			Janssen
Arthralgia; Cardiovascular	Simponi			S				Janssen
Disorder; Contraindicated	Remicade			S	Subcutaneous			Janssen
Product Administered;	Remicade			S	Unknown			Janssen
Drug Hypersensitivity;	Infliximab, Recombinant			S	Unknown			Janssen
Drug Ineffective;	Infliximab, Recombinant			S	Unknown			Janssen
Inflammation; Joint	Adalimumab			S	Unknown			Not Reported
Swelling; Muscle Spasms;	Leflunomide			S	Unknown			Not Reported
Red Blood Cell	Cimzia			S	Subcutaneous			Not Reported
Sedimentation Rate	Enbrel			S	Unknown			Not Reported
Increased; Urticaria	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

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

Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Azathioprine	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Minocycline	C	Unknown	Not Reported
Penicillamine	C	Unknown	Not Reported
Prednisolone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported
Actemra	C	Unknown	Not Reported
Phenylbutazone	C	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17666050	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3361715-00		80 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt	Kaletra			S	Oral			Not Reported	
Prolonged; Off Label Use	Plaquenil			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17667413	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS			Unknown	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

LLC-FR-
2020VAL000290

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Ventricular Tachycardia	Furosemide			S	Intravenous (not otherwise specified)	2 Df, Qd		Validus
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Perfalgan			C		Unk		Not Reported
	Noradrenalin /00127501/			C		Unk		Not Reported
	Midazolam			C		Unk		Not Reported
	Tazocilline			C		Unk		Not Reported
	Transipeg /00754501/			C		Unk		Not Reported
	Potassium Chloride			C		Unk		Not Reported
	Nimbex /01302502/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17673259	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009906		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Blood Creatinine Increased; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain;	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Abatacept			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported

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

Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Gabapentin	C	Oral	400 Mg, Tid	Not Reported
	Tylenol Arthritis	C	Unknown	650 Mg, Qid	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17695364	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020073		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17695454	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2752444-00			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Intolerance; Drug Intolerance; Joint Swelling;	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Subcutaneous			Not Reported
	Imuran			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported

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

Off Label Use; Product	Methotrexate	S	Subcutaneous	Not Reported
Use Issue; Therapeutic	Methotrexate	S	Oral	Not Reported
Product Effect Decreased;	Sulfasalazine	S	Unknown	Not Reported
Therapeutic Product Effect	Enbrel	S	Subcutaneous	Not Reported
Incomplete; Therapeutic	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Product Effect Incomplete	Rituxan	S	Intravenous (not otherwise specified)	Day 1 And Day 15 Every 6 Months
	Actemra	S	Unknown	Not Reported
	Lederle Leucovorin	S	Unknown	Not Reported
	Prevnar 13	S	Intramuscular	Not Reported
	Depo-Medrol With Lidocaine	S	Unknown	40-10 Mg/MI
	Apo-Prednisone	S	Unknown	Taper Monthly
	Ketoprofen	S	Topical	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Leucovorin Calcium	S	Unknown	Not Reported
	Azathioprine Sodium	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586578		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Chronic	Rituximab			S	Unknown			Not Reported
Kidney Disease;	Mycophenolate Mofetil			S	Unknown			Not Reported
Contraindicated Product	Tocilizumab			S	Unknown			Not Reported
Administered;	Amoxicillin			S	Unknown			Not Reported
Diverticulitis; Drug	Trihydrate;Clavulanate							
Hypersensitivity; Drug	Potassium							
Ineffective; Drug	Azathioprine			S	Unknown			Not Reported
Intolerance; Interstitial								
Lung Disease; Synovitis;								

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

Systemic Lupus Erythematosus; Treatment Failure	Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696576	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1224670		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Herpes Simplex; Herpes Simplex Hepatitis; Thrombocytopenia	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva	
	Prednisone			S	Unknown	5 Milligram Daily; Daily		Actavis	
	Acetaminophen			C	Unknown	Estimated 6g		Not Reported	
	Metronidazole			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696653	EXPEDITED (15-DAY)		LT	CA-ROCHE-2585146		27 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Procytox			S	Intravenous (not otherwise specified)			Not Reported	

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

Procytox	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Diphenhydramine	C	Oral	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Methylprednisolone Sodium Succinate	C	Intravenous (not otherwise specified)	Not Reported
Methylprednisolone Sodium Succinate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696778	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584640			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported
Blood Creatinine Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Mobility Decreased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Rheumatoid Arthritis	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696796	EXPEDITED (15-DAY)		OT	AU-ROCHE-2586107			Female	AUS

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Neuropathy Peripheral; Vision Blurred	Tocilizumab			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Lovan			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696808	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3374580-00		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hyponatraemia	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S				Not Reported	
	Dolquine			S	Oral			Not Reported	
	Levofloxacino			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696824	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585673		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported	
	Amoxicillin;Clavulanate			S	Unknown			Not Reported	
	Potassium Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17696968	EXPEDITED (15-DAY)	HO		CA-ROCHE-2585153		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Celebrex			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697005	EXPEDITED (15-DAY)	OT		MX-ADVANSZ PHARMA-202004003548			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Blindness	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk	Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697018	EXPEDITED (15-DAY)		OT	US-VELOXIS PHARMACEUTICALS- 2018VELUS-000310			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Heart Rate Deceleration Abnormality; Lymphocytopenia Neonatal; Off Label Use; Premature Baby; Thymus Disorder	Envarsus Xr			S	Transplacental	Unk		Veloxis Pharmaceuticals
	Envarsus Xr			S				Veloxis Pharmaceuticals
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S				Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Azathioprine			S				Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Prednisone			S				Not Reported
	Steroids			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697203	EXPEDITED (15-DAY)		DS, OT	CA- GLAXOSMITHKLINE- CA2020068659		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Voltaren (Diclofenac Sodium)			S	Unknown	Unk		Glaxosmithkline
	Diclofenac			S	Unknown	Unk		Glaxosmithkline
	Diclofenac Potassium			S	Unknown	Unk		Glaxosmithkline
	Codeine			S	Unknown	Unk		Glaxosmithkline
	Actemra			S	Unknown	Unk		Not Reported
	Celebrex			S	Unknown	Unk		Not Reported
	Cimzia (Certolizumab Pegol)			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported

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Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697218	EXPEDITED (15-DAY)		OT	ES-CIPLA LTD.- 2020ES02876			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Milligram, Qd (Per Day; 500 Mg/24h)		Cipla	
	Dolquine			S	Oral	200 Milligram, Per Day (1 Comp/24h)		Not Reported	
	Metronidazol [Metronidazole]			S	Oral	Unk		Not Reported	
	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697219	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1226965		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Parenteral			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Azathioprine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697355	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226540			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697469	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226211		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Daily		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697552	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2020SA101001		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer; Unevaluable Event	Hydroxychloroquine Sulfate			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S	Subcutaneous	12.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	12 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		12.5mg, Qw		Not Reported
	Methotrexate			S		10 Mg, Qw		Not Reported
	Methotrexate			S		10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	15.0 Mg Qw		Not Reported
	Methotrexate			S	Subcutaneous	17.5 Mg Qw		Not Reported
	Methotrexate			S	Oral	10 Mg Qw		Not Reported
	Methotrexate			S		70.0 Mg, Qw		Not Reported
	Methotrexate			S		12.5 Mg, Qw		Not Reported
	Methotrexate			S		12.0 Mg, Qw		Not Reported
	Methotrexate			S		10 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qow		Not Reported
	Methotrexate			S	Subcutaneous	10 Mg, Qw		Not Reported
	Methotrexate			S		12 Mg, Qw		Not Reported
	Alendronate Sodium			S		70 Mg, Qw		Not Reported
	Leflunomide			S				Sanofi
	Leflunomide			S	Oral			Sanofi

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Sulfasalazine	S		500 Mg	Not Reported
Codeine	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	50 Mg, Qm	Not Reported
Actemra	S		360 Mg	Not Reported
Actemra	S		360 Mg	Not Reported
Actemra	S		360 Mg, Qm	Not Reported
Actemra	S		2.68 Mg, Q4w	Not Reported
Enbrel	S		50 Mg	Not Reported
Enbrel	S		25 Mg	Not Reported
Humira	S	Subcutaneous	40 Mg	Not Reported
Orencia	S		780 Mg, Qw	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Q12h	Not Reported
Ciclosporin	C			Not Reported
Prednisone	C			Not Reported
Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697667	EXPEDITED (15-DAY)	DS		CA-TEVA-2020-CA-1226215		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amyotrophic Lateral Sclerosis	Leflunomide			S	Unknown			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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Methotrexate	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697668	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226208		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Leflunomide			S	Unknown			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697696	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033213		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Pain In Extremity; Peripheral Swelling;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

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Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697751	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226514		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous	12.5 Milligram Daily;		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous	100 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17698407	EXPEDITED (15-DAY)		DE, OT	ES-FRESENIUS KABI-FK202003872		21 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unk		Fresenius Medical Care	
	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Oral	400mg/24h		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17698625	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226709			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Naproxen			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17698783	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1226193		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Aleve			C	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Simponi			C	Subcutaneous			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699111	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226577			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	

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Enzyme Increased; Pneumonia	Actemra	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699160	EXPEDITED (15-DAY)		OT	CA-SA-2020SA101058			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia; Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosis; Vasculitis	Arava			S		Unk		Sanofi	
	Colchicine			S				Not Reported	
	Celecoxib			S				Not Reported	
	Estradiol			S	Topical	Unk Unk, Qd		Not Reported	
	Prednisone			S		50 Mg		Not Reported	
	Meloxicam			S				Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Plaquenil			S		2 Df, Qd		Sanofi	
	Salbutamol Sulfate			S				Not Reported	
	Sulfasalazine			S				Not Reported	
	Belimumab			S				Not Reported	
	Breo Ellipta			S	Respiratory (inhalation)			Not Reported	
	Dexilant			S	Oral	60 Mg, Qd		Not Reported	
	Rituximab			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585119		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tridural			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699586	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585610		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Actemra	S	Unknown	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699673	NON-EXPEDITED			US-APPCO PHARMA LLC-2083078		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Substitution Issue	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699823	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226217		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported

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

Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Leflunomide	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Vioxx	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226721		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported	

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

Xeljanz			C	Oral	10 Gram Daily;			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699840	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226582			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Milligram Daily;		Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Plaquenil[Hydroxychloroquine Phosphate]			C	Oral	400 Milligram Daily;		Not Reported	
	Xeljanz			C	Oral			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Simponi			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699841	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226428		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	

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

Exfoliation; Rash; Secretion Discharge; Spinal Stenosis	Anakinra	S	Subcutaneous	100 Milligram Daily;	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699865	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226602		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo- Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699945	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226474		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Elavil			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Imitrex [Sumatriptan]			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699946	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226195			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; C-Reactive Protein Increased;	Leflunomide			S	Unknown			Barr
Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Joint Destruction; Joint Effusion;	Methotrexate			S	Unknown			Barr
Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Vascular Access Complication; White Blood Cell Count Increased	Abatacept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699990	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428562		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colon Neoplasm; Injection Site Reaction; Psoriasis;	Simponi			S	Subcutaneous			Janssen

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Rheumatoid Arthritis	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700384	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004003668			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Rheumatoid Arthritis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		Unk		Concordia
	Narcan			S		Unk		Not Reported
	Cyclobenzaprine Hcl			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Wellbutrin XI			S		Er 24h		Not Reported
	Wellbutrin XI			S		Er 24h		Not Reported
	Prednisone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700739	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020169		54 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Haemolytic Anaemia; Hepatitis; Hyperbilirubinaemia; Rectal Haemorrhage	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17702515	EXPEDITED (15-DAY)		LT	FR-BAUSCH-BL-2020-011521		59 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral			Not Reported	
	Loxapine Base			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Theralene			S	Oral			Not Reported	
	Paracetamol			C	Oral			Not Reported	
	Nicopatch			C	Transdermal	Transdermal Device Of 17.5 Mg / 10 Cm2		Not Reported	
	Diazepam			C	Oral			Not Reported	
	Atorvastatine			C	Oral			Not Reported	
	Nicotine			C	Oral			Not Reported	
	Macrogol 4000			C	Oral			Not Reported	
	Nebivolol			C	Oral			Not Reported	
	Zopiclone			C	Oral			Not Reported	
	Ramipril			C	Oral			Not Reported	
	Akineton			C	Oral			Not Reported	
	Ezetimibe			C	Oral			Not Reported	
	Kardegic			C	Oral	Sachet Dose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17703331	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-033234			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Orencia			S	Unknown	750 Milligram		Bristol Myers Squibb	
	Actemra			S	Unknown	8 Milligram		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	

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Leflunomide	S	Unknown	20 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qd	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Meloxicam	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17703332	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-033240			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Orencia			S	Intravenous (not otherwise specified)	0.75 Milligram, Qmo		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8.0 Milligram/Kilogram, Qmo		Not Reported	
	Apo-Azathioprine			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	40 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Not Reported	
	Methotrexate			S	Subcutaneous	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17703341	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-033127			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Condition Aggravated; Deep Vein Thrombosis; Diarrhoea; Rash; Skin Infection; Systemic Lupus Erythematosis; Transaminases Increased; Treatment Failure	Orencia	S	Subcutaneous	125 Milligram, Qwk	Bristol Myers Squibb
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Myochrysine	S	Intramuscular	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Pariet	C	Unknown	20 Milligram, Qd	Not Reported
	Folic Acid	C	Unknown	5 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17703445	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226725		59 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Zopiclone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

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

Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17704032	DIRECT	Y	OT			32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia	Hydroxychloroquine 200 Mg			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	11433670	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-056507			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Intravenous (not otherwise specified)	1000 Milligram, Qmo		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	20 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, Qd		Not Reported
	Apo Hydroxyquine			S	Oral	400 Milligram		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported
	Arava			S	Oral	10 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk, Qd		Not Reported
	Hydroxychloroquine			S	Oral	400 Milligram, Qd		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Qd		Not Reported

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

Leflunomide	S	Oral	10 Milligram, Qd	Not Reported
Naprosyn [Naproxen]	S	Unknown	Unk Prn	Not Reported
Methotrexate	S	Intramuscular	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Naproxen	S	Unknown	Unk Unk, Prn	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Cardio Aspirin	C	Unknown	81 Milligram	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Lantus	C	Subcutaneous	Unk	Not Reported
Insulin [Insulin Human]	C	Unknown	Unk	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk	Not Reported
Calcium [Calcium Gluconate]	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk Prn	Not Reported
Lozide [Gliclazide]	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Vitamin D Nos	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	11619820	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-15K-028-1477576-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
Contraindicated Product Administered; Drug	Xeljanz			S	Oral			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	

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

Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Deformity; Hand Deformity; Hand Deformity; Hypertension; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Musculoskeletal Disorder; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Cyclical Frequency	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Actonel	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Risedronate Sodium	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	11878759	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20151223430			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Back Injury;	Simponi			S	Subcutaneous			Janssen	

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

Confusional State; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Hospitalisation; Injury; Muscular Weakness; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Methotrexate Sodium Sulfasalazine Hydroxychloroquine Arava Humira Orencia Rituxan Rituxan Plaquenil Methotrexate Hydroxychloroquine Cimzia Enbrel	S S S S S S S S S S S C C	Unknown Unknown Unknown Unknown Subcutaneous Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Oral Unknown Subcutaneous Unknown	Cyclic(Every 2 Weeks) 40 Mg/0.8 MI	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	12791907	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2016449402		66 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Methotrexate Sodium			S		7.5 Mg, Every 10 Days		Pfizer
	Certolizumab Pegol			S		200 Mg, Every Other Week		Not Reported
	Certolizumab Pegol			S		Tapered To One Injection Every 21 Days		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	13091523	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2016AP016274			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Unknown	25 Mg, Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S	Subcutaneous	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not	Unk		Not Reported

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

	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Certolizumab Pegol	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	13109301	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-065623		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C- Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Joint Destruction; Joint Effusion; Joint Injury; Juvenile	Orencia			S	Intravenous (not otherwise specified)	250 Milligram, Qmo		Bristol Myers Squibb
	Orencia			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Intra-articular	Unk		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Oral	5 Milligram, Qd		Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Triamcinolone Acetonide			S	Unknown			Bristol Myers Squibb
	Enbrel			S	Subcutaneous	12.5 Milligram, Qd		Not Reported
	Enbrel			S	Subcutaneous	25 Milligram, Q2wk		Not Reported
	Enbrel			S	Unknown	12.5 Milligram, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram/Sq. Meter, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram		Not Reported

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

Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Hydroxychloroquine	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
	Hydroxychloroquine	S	Oral	5 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Infliximab	S	Unknown	5 Milligram	Not Reported
	Infliximab	S	Unknown	3 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown		Not Reported
	Kineret	S	Subcutaneous	50 Milligram, Qd	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, Qwk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Milligram, 2 Every 1 Week	Not Reported
	Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Gram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	70 Milligram	Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]	S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Qwk	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Oral	3 Milligram, Bid	Not Reported
	Apo-Prednisone	S	Oral	5 Milligram, Bid	Not Reported
	Apo Triamcinolone Aq	S	Unknown	Unk	Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported

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

Adalimumab	S	Unknown		Not Reported
Anakinra	S	Subcutaneous	50 Milligram, Qd	Not Reported
Anakinra	S	Unknown	50 Milligram, Qwk	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Milligram, Q2wk	Not Reported
Tocilizumab	S	Unknown		Not Reported
Triamcinolone	S	Subcutaneous	25 Milligram, Q2wk	Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Triamcinolone	S	Unknown		Not Reported
Apo-Naproxen	S	Unknown	Unk	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	70.0 Gram	Not Reported
Gamastan	S	Intramuscular	70 Gram	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Dosage Form	Not Reported
Hydroxychloroquine Sulfate	S	Oral	5 Milligram/Kilogram, Qd	Not Reported
Naproxen Sodium	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	25 Milligram(2 Every 1 Week)	Not Reported
Etanercept	S	Unknown	12.5 Milligram, Qwk	Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	13517171	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-038205		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Event; Alopecia;	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb	

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

Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Orencia	S	Subcutaneous	Unk	Bristol Myers Squibb
	Actemra	S	Subcutaneous	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Milligram	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfathalidine	S	Oral	500 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported

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

Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Milligram, Bid	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	13667720	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951961		37 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Bone Disorder; C-Reactive Protein Abnormal; Chest Pain; Contraindicated Product Administered; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	13854282	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-070658			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Orencia			S	Unknown	125 Milligram, Qwk		Bristol Myers Squibb
	Enbrel			S	Subcutaneous	Unk Unk, Qwk		Not Reported
	Enbrel			S	Unknown	50 Milligram, Q2wk		Not Reported
	Enbrel			S	Subcutaneous	1 Dosage Form		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

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

Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unk, Q2wk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Advil [Mefenamic Acid]	C	Unknown		Not Reported
Prednisone	C	Oral	6 Milligram, Qd	Not Reported
Prednisone	C	Oral	10 Milligram, Qd	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Dequalinium Chloride	C	Unknown	Unk	Not Reported
Mefenamic Acid	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown		Not Reported
Advil [Ibuprofen]	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	13856327	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-070350		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
Alopecia; Arthralgia; Blood	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
Cholesterol Increased;	Actemra			S	Unknown	Unk		Not Reported	
Drug Ineffective; General	Cimzia			S	Subcutaneous	400 Milligram		Not Reported	
Physical Health	Enbrel			S	Subcutaneous	50 Milligram		Not Reported	
Deterioration; Headache;									
Hypersensitivity;									
Hypertension; Joint									

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

Swelling; Maternal Exposure During Pregnancy;	Humira	S	Subcutaneous	40 Milligram	Not Reported
Musculoskeletal Stiffness; Pain; Pemphigus;	Remicade	S	Intravenous (not otherwise specified)		Not Reported
Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis;	Simponi	S	Subcutaneous		Not Reported
Swelling; Swollen Joint Count Increased;	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Synovitis; Systemic Lupus Erythematosus;	Xeljanz	S	Unknown	Unk	Not Reported
Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Diclofenac	S	Unknown	50 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
	Arava	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	14757587	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009591			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	14778860	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009970		52 YR	Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	14951428	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018213596		56 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Retinal Toxicity	Docetaxel			S		Unk, Cyclic 21-Day Cycles, 4 Cycles		Pfizer
	Hydroxychloroquine			S		Daily Dose: 7.01 Mg/Kg And Total Cumulative Dose 402 G		Not Reported
	Anastrozole			S		Unk Total Of 4 Months		Not Reported
	Cyclophosphamide			S		Unk, Cyclic 21-Day Cycles, 4 Cycles		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	15032295	EXPEDITED (15-DAY)		OT	US-SA-2018SA149938		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Anastrozole			S				Not Reported
	Hydroxychloroquine			S		Daily Dose: 7.01 Mg/Kg		Sanofi
	Cyclophosphamide			S		21-Day Cycles		Not Reported
	Docetaxel			S		21-Day Cycles		Sanofi

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	15335557	EXPEDITED (15-DAY)		HO, LT, OT	MX-PFIZER INC-2018348261		67 YR	Female	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Bradycardia; Cardiac Failure Acute; Drug Interaction; Long Qt Syndrome; Presyncope; Sinus Bradycardia	Amiodarone Hcl			S	Oral	900 Mg, Daily (Every 24 Hours), Bolus Subsequent Dose		Pfizer
	Amiodarone Hcl			S	Unknown	200 Mg, 4x/Day		Pfizer
	Amiodarone Hcl			S	Intravenous (not otherwise specified)	300 Mg, Unk (Bolus)		Pfizer
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		200 Mg, Daily (Every 24 Hours)		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg, 4x/Day		Not Reported

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

	Furosemide	S	Unknown	20 Mg, 4x/Day	Not Reported
	Warfarin Sodium	S	Unknown	2.5 Mg, 4x/Day	Not Reported
	Digoxin	C		Unk	Not Reported
	Digoxin	C			Not Reported
	Digoxin	C			Not Reported
	Spironolactone	C		Unk	Not Reported
	Spironolactone	C			Not Reported
	Spironolactone	C			Not Reported
	Metoprolol	C		Unk	Not Reported
	Metoprolol	C			Not Reported
	Metoprolol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	15411121	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-185070		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pruritus; Rash Maculo-Papular	Perindopril			S	Oral	Unk		Not Reported	
	Perindopril			S	Unknown	Unk		Not Reported	
	Repaglinide			S	Oral	()		Sun	
	Plaquenil			S	Oral	200 Mg/Jour		Not Reported	
	Cortancyl			S	Oral	10-20µg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	15682732	EXPEDITED (15-DAY)	DS, LT, OT		PHHY2018CA168554		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac			S	Unknown	Unk		Novartis	
Abdominal Pain Upper;	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported	
Alopecia; Anti-Cyclic	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported	
Citrullinated Peptide	Leflunomide			S	Oral			Not Reported	
Antibody Positive;									
Arthropathy; Blister;									
Condition Aggravated;									

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

Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Injury; Intentional Product Use Issue; Joint Swelling; Live Birth; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Zyrtec-D	S	Unknown	10 Mg, Unk	Not Reported
	Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Dosage Form: Unspecified	Not Reported
	Topicort	S	Cutaneous	Unk	Not Reported
	Cirrus	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Arava	S	Oral	20 Mg	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous	Dosage Form: Solution	Not Reported
	Fosamax	S	Oral		Not Reported
	Plaquenil	S	Oral	400 Mg, Qd	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Cetirizine	S	Unknown	10 Mg, Unk	Not Reported
	Cetirizine	S			Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Dosage Form: Lyophilized Powder	Not Reported
	Apo-Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Once Daily (Qd)	Not Reported

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Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
Apo-Prednisone	S	Oral		Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous	Dosage Form: Unspecified	Not Reported
Humira	S	Subcutaneous	40 Mg, 0.8ml	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Oral	1000 Mg, Bid	Not Reported
Sulfathalidine	S	Oral	500 Mg, Unk	Not Reported
Tofacitinib	S	Unknown	5 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	1000 Mg, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, 2x/Day (Bid)	Not Reported
Paracetamol	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Mg	Not Reported
Reactine (Cetirizine Hydrochloride)	S			Not Reported
Stelara	S	Unknown		Not Reported
Cortisone	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous	25 Mg	Not Reported
Sarilumab	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	16001840	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1017013		78 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Discomfort;	Diclofenac Potassium	S	Unknown	Actavis
Abdominal Pain Upper;	Diclofenac Potassium	S	Unknown	Actavis
Abnormal Loss Of Weight;	Diclofenac Potassium	S	Unknown	Actavis
Adverse Drug Reaction;	Diclofenac Potassium	S	Unknown	Actavis
Adverse Reaction;	Diclofenac Potassium	S		Actavis
Arthralgia; Arthropathy;	Acetylsalicylic Acid	S	Unknown	Not Reported
Deafness; Deafness	Acetylsalicylic Acid	S	Oral	Not Reported
Transitory; Decreased	Acetylsalicylic Acid	S		Not Reported
Appetite; Dizziness; Drug	Acetylsalicylic Acid	S		Not Reported
Hypersensitivity; Ear	Acetylsalicylic Acid	S		Not Reported
Infection; Eating Disorder;	Methotrexate	S	Unknown	Barr
Feeding Disorder; Foot	Methotrexate	S	Unknown	Barr
Operation; Functional	Methotrexate	S		Barr
Gastrointestinal Disorder;	Methotrexate	S		Barr
Gastrointestinal Disorder;	Methotrexate	S		Barr
Gastrointestinal Pain;	Naproxen	S	Unknown	Teva
Headache; Hypophagia;	Naproxen	S		Teva
Mobility Decreased;	Naproxen	S		Teva
Musculoskeletal Disorder;	Naproxen	S		Teva
Nausea; Off Label Use;	Sulfamethoxazole And	S	Unknown	Actavis
Pharyngitis; Shoulder	Trimethoprim	S		Actavis
Arthroplasty; Vomiting;	Sulfamethoxazole And	S		Actavis
Weight Decreased	Trimethoprim	S		Actavis
	Sulfamethoxazole And	S		Actavis
	Trimethoprim	S		Actavis
	Sulfamethoxazole And	S		Actavis
	Trimethoprim	S	Unknown	Actavis
	Ibuprofen	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Arava	S		Not Reported
	Aspirin	S	Oral	Not Reported
	Aspirin	S		Not Reported
	Aspirin	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported

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Enbrel	S		Not Reported
Gold Injections	S	Unknown	Not Reported
Gold Injections	S		Not Reported
Gold Injections	S		Not Reported
Gold Injections	S		Not Reported
Humira (Adalimumab)	S	Subcutaneous	Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Humira (Adalimumab)	S		Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Unknown	Not Reported
Hydroxychloroquine Sulfate Tablets	S	Oral	Not Reported
Hydroxychloroquine Sulfate Tablets	S		Not Reported
Motrin	S	Unknown	Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Motrin	S		Not Reported
Plaquenil	S	Oral	Not Reported
Plaquenil	S		Not Reported
Plaquenil	S		Not Reported
Sodium Aurothiomalate Injection Bp	S	Parenteral	Not Reported
Sodium Aurothiomalate Injection Bp	S	Unknown	Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Sodium Aurothiomalate Injection Bp	S		Not Reported
Vitamin C	S	Unknown	Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Vitamin C	S		Not Reported
Tramadol Hydrochloride	S	Unknown	Not Reported
Naprosyn	S	Unknown	Not Reported

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Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Naprosyn	S		Not Reported
Voltaren	S	Unknown	Not Reported
Acetylsalicylic Acid/Clopidogrel	S	Unknown	Not Reported
Apo-Diclofenac	S	Unknown	Not Reported
Apo-Sulfatrim	S	Unknown	Not Reported
Tramadol Hydrochloride	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	16047193	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1020789		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Methotrexate			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Leflunomide			S	Unknown			Barr
	Celebrex			S	Oral	200milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine /00072603/			C	Unknown	400 Milligram Daily;		Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	16397631	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-210010			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Infection	Diclofenac			S	Unknown	Unk ()		Sun	
Reactivation;	Hydroxychloroquine			S	Unknown	Unk ()		Sun	
Leishmaniasis; Sensation	Lansoprazole			C	Unknown	Unk		Not Reported	
Of Foreign Body; Visceral	Lansoprazole			C	Unknown	Unk ()		Not Reported	
Leishmaniasis; Visceral									
Leishmaniasis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	16461090	EXPEDITED (15-DAY)		CA, DE, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-211015			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Bowing Of	Esomeprazole			S	Transplacental	20 Milligram, Daily		Sun	
Long Bones; Congenital	Plaquenil 200 Mg, Comprime			S	Transplacental	400 Milligram, Daily		Not Reported	
Osteodystrophy; Foetal	Enrobe								
Growth Restriction; Low	Diffu K, Gelule			S	Transplacental	1 Dosage Form, Daily		Not Reported	
Birth Weight Baby;	Cortancyl 5 Mg, Comprime			S	Transplacental	1 Dosage Form, Daily		Not Reported	
Maternal Exposure During	Imurel			S	Transplacental	150 Milligram, Daily		Not Reported	
Pregnancy; Patent Ductus									
Arteriosus; Premature									
Baby; Premature									
Separation Of Placenta;									
Right-To-Left Cardiac									
Shunt									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	16544910	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC- 2019288608		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product	Methotrexate Sodium			S		Unk		Pfizer	

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

Use In Unapproved Indication; West Nile Viral Infection	Methylprednisolone	S	Unk (High Dose)	Pfizer
	Rituximab	S	Unk	Pfizer
	Hydroxychloroquine	S	Unk	Not Reported
	Prednisone	S	6 Mg, Daily (Tapering Of The Dose)	Not Reported
	Mycophenolate Mofetil	S	Unk	Not Reported
	Trimethoprim Sulfamethoxazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	16576751	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-034879		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Acne; Appendicitis Perforated; Arthralgia; Asthenia; Bradycardia; Depressed Mood; Erythema; Fatigue; Gastrointestinal Disorder; Headache; Hypertension; Lethargy; Malaise; Nausea; Pain; Pain In Extremity; Peritonitis; Rash; Synovial Cyst	Abatacept			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb	
	Abatacept			S	Unknown			Bristol Myers Squibb	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Ciprallex [Escitalopram]			C	Unknown	Unk		Not Reported	
	Estradiol			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Colace			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17165875	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1151435			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Erosion; Drug Ineffective; Pneumocystis	Methotrexate			S	Unknown			Barr	

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Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Leflunomide	S	Unknown	400 Milligram Daily;	Barr
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17188130	EXPEDITED (15-DAY)		OT	JP-ADVANSZ PHARMA- GSH201901-000131			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Photopsia; Retinal Dystrophy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day, Alternately		Concordia
	Cellcept			C		Unk		Not Reported
	Arotinolol Hydrochloride			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Takecab			C		Unk		Not Reported
	Rivotril			C		Unk		Not Reported
	Bonoteo			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17200794	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019232735			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citruinated Peptide Antibody Positive; Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition Aggravated;	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline
	Desoximetasone			S	Oral	Unk		Glaxosmithkline
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline

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

Contraindicated Product	Folic Acid	S	Unknown	5 Milligram	Glaxosmithkline
Administered; Decreased	Folic Acid	S	Unknown	0.5 Milligram	Glaxosmithkline
Appetite; Discomfort; Drug	Paracetamol	S	Unknown	Unk	Glaxosmithkline
Ineffective; Drug	Diclofenac Sodium	S	Unknown	Unk	Glaxosmithkline
Intolerance; Fatigue;	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Glaxosmithkline
General Physical Health	Reactine (Cetirizine	S	Unknown	Unk	Glaxosmithkline
Deterioration;	Hydrochloride)				
Glossodynia; Hand	Cimzia	S	Subcutaneous	400 Mg	Not Reported
Deformity; Headache;	Cimzia	S			Not Reported
Hepatic Enzyme	Cetirizine Hydrochloride +	S	Unknown	Unk	Not Reported
Increased; Hip	Pseudoephedrine Hydrochloride				
Arthroplasty;	Cetirizine Hydrochloride +	S			Not Reported
Hypersensitivity;	Pseudoephedrine Hydrochloride				
Hypertension;	Plaquenil (Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily	Not Reported
Hypoaesthesia; Infusion	Sulfate)			(Qd)	
Related Reaction; Joint	Remicade	S	Intravenous (not	400 Mg, We, 400	Not Reported
Swelling; Knee			otherwise specified)	Milligram, Weekly (Qw)	
Arthroplasty; Malaise;	Enbrel	S	Subcutaneous	50 Milligram, Weekly (Qw)	Not Reported
Maternal Exposure During	Actemra	S	Intravenous (not	Unk	Not Reported
Pregnancy; Mobility			otherwise specified)		
Decreased;	Humira	S	Subcutaneous	Solution	Not Reported
Musculoskeletal Stiffness;	Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Off Label Use; Pain;	Xeljanz	S	Oral	5 Milligram, 2x/Week	Not Reported
Pemphigus; Pericarditis;	Apo Prednison	S	Unknown	Unk	Not Reported
Product Use Issue; Rash;	Apo Prednison	S	Unknown	Unk	Not Reported
Rheumatic Fever;	Arava	S	Oral	Unk	Not Reported
Rheumatoid Arthritis;	Simponi	S	Subcutaneous	50 Milligram, Monthly	Not Reported
Rheumatoid Factor				(Qm)	
Positive; Swelling; Swollen	Simponi	S			Not Reported
Joint Count Increased;	Fosamax	S	Oral	Unk	Not Reported
Synovitis; Systemic Lupus	Simponi	S	Subcutaneous	Unk	Not Reported
Erythematousus;	Simponi	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Hydroxychloroquine	S	Unknown	400 Milligram, Once Daily	Not Reported
Decreased; Treatment					
Failure; Type 2 Diabetes					
Mellitus; Wound					

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

			(Qd)	
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Subcutaneous	Solution	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Once Daily (Qd)	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
Methotrexate	S	Unknown	20 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Oral	20 Milligram, Once Daily (Qd)	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Winpred	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Topicort Lp	S	Subcutaneous	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported
Otezla	S	Oral	3 Milligram, 2x/Day (Bid)	Not Reported

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

Prednisone	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Tocilizumab	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Ustekinumab	S	Intravenous (not otherwise specified)	45 Milligram	Not Reported
Topicort Lp	S	Oral	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram, Once Daily (Qd)	Glaxosmithkline
Desoximetasone	C	Oral	25 Milligram, Weekly (Qw)	Glaxosmithkline
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	C	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Salazopyrine	C	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Tofacitinib Citrate	C	Oral	5 Milligram, Weekly (Qw)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17215818	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-1952857US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Actonel			S	Unknown	35 Mg, Q Week		Allergan	
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss	Actonel			S	Unknown	35 Mg, Q Week		Allergan	
	Actonel			S	Unknown	35 Mg, Q Week		Allergan	
	Actemra			S	Subcutaneous	Unk Mg/Kg		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported	
	Anakinra			S	Subcutaneous	100 Mg		Not Reported	
	Anakinra			S	Subcutaneous	100 Mg		Not Reported	
	Apo-Leflunomide			S	Oral	20 Mg, Unk		Not Reported	

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Of Consciousness;	Arava	S	Oral	20 Mg, Qd	Not Reported
Mobility Decreased;	Cimzia	S	Subcutaneous		Not Reported
Nausea; Nodule; Off Label	Enbrel	S	Subcutaneous	50 Mg	Not Reported
Use; Pulmonary Fibrosis;	Gold	S	Unknown		Not Reported
Red Blood Cell	Humira	S	Subcutaneous	40 Mg, Q2weeks	Not Reported
Sedimentation Rate	Hydroxychloroquine	S	Unknown	300 Mg, Qd	Not Reported
Abnormal; Rheumatoid	Hydroxychloroquine	S	Oral	20 Unk	Not Reported
Arthritis; Rheumatoid	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Factor Positive; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	300 Mg	Not Reported
	Leflunomide	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil	S	Unknown	300 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17425099	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2020023487		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction;	Benlysta			S	Intravenous (not otherwise specified)	Unk Unk, We		Glaxosmithkline	
Anaemia; Dizziness;	Cipro			S	Unknown	Unk		Glaxosmithkline	
Haemolytic Uraemic	Plaquenil			S	Unknown	Unk		Not Reported	
Syndrome; Hypotension;									
Nausea; Product Dose									
Omission; Renal Injury;									

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Urinary Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17543214	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-020534			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosis; Wound	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Alendronate Sodium			S	Oral	Unk		Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported	
	Cortisone Acetate			S	Unknown	Unk		Not Reported	
	Desoximetasone			S	Oral	Unk		Not Reported	
	Diclofenac Sodium			S	Unknown	Unk		Not Reported	
	Diclofenac			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Folic Acid			S	Unknown	1 Milligram		Not Reported	
	Folic Acid			S	Unknown	5 Milligram		Not Reported	
	Folic Acid			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Fosamax			S	Oral	Unk		Not Reported	

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Hydroxychloroquine	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown		Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17605652	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332789		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration 2.0 Years		Janssen

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

Intolerance; Off Label Use;	Actemra	S	Unknown		Not Reported
Product Use Issue;	Arava	S	Oral		Not Reported
Psoriatic Arthropathy;	Azathioprine	S	Unknown		Not Reported
Rash; Rheumatoid	Azathioprine	S	Unknown		Not Reported
Arthritis; Sciatica;	Certolizumab Pegol	S	Subcutaneous		Not Reported
Sinusitis; Therapeutic	Certolizumab Pegol	S	Unknown		Not Reported
Product Effect Incomplete;	Ciclosporin	S	Vaginal		Not Reported
Treatment Failure	Ciclosporin	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Pregabalin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Lyrica	S	Vaginal		Not Reported
	Piroxicam	C			Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17623406	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200342133			Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Decreased; Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Joint Swelling; Rheumatoid Arthritis; Synovitis; X-Ray Abnormal	Simponi			S	Subcutaneous			Janssen
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	5 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17623534	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200340450		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose;	Simponi			S	Subcutaneous			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

Rheumatoid Arthritis;	Methotrexate	S	Subcutaneous	Not Reported
Synovitis; Systemic Lupus	Methotrexate	S	Oral	Not Reported
Erythematosis;	Methotrexate	S	Subcutaneous	Not Reported
Underdose; Vomiting	Methotrexate	S	Subcutaneous	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naprosyn /00256201/	C	Unknown	Not Reported
	Naprosyn /00256201/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17641316	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-029045			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
Alopecia; Arthropathy;	Actemra			S	Unknown			Not Reported
Glossodynia; Maternal	Arava			S	Oral	Unk		Not Reported
Exposure During	Arava			S	Unknown	Unk		Not Reported
Pregnancy; Pain;	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Pemphigus; Rheumatoid	Cimzia			S	Subcutaneous	Unk		Not Reported
Arthritis; Systemic Lupus	Diclofenac Sodium			S	Unknown	Unk		Not Reported
Erythematosis	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	1 Milligram		Not Reported
	Fosamax			S	Oral	Unk		Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17666360	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009894		35 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Rash; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported

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

Sulfasalazine	S	Unknown	300 Mg, Qd	Not Reported
Xeljanz	C	Oral	5.0 Mg, Bid	Not Reported
Magnesium	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701054	EXPEDITED (15-DAY)		CA, DS, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-244979			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chondrodystrophy; Chondropathy; Dysmorphism; Low Birth Weight Baby; Maternal Exposure During Pregnancy	Paracetamol		Y	S	Transplacental	Unk ()		Ohm Lab	
	Keppra			S	Transplacental	Unk ()		Not Reported	
	Trileptal			S	Transplacental	Unk ()		Not Reported	
	Plaquenil			S	Transplacental	Unk ()		Not Reported	
	Kaleorid			C	Transplacental	Unk		Not Reported	
	Orocal D3			C	Transplacental	Unk		Not Reported	
	Speciafoldine			C	Transplacental	Unk ()		Not Reported	
	Cortancyl			C	Transplacental	Unk ()		Not Reported	
	Diffu-K			C	Transplacental	Unk ()		Not Reported	
	Actonel			C	Transplacental	Unk ()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701285	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-244571		31 YR	Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine			S	Unknown	Unk		Sun	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701299	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-244572		42 YR	Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Febrile Neutrophilic Dermatitis	Hydroxychloroquine			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701322	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-019746			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Systemic Lupus Erythematosus	Celecoxib Capsules			S	Oral	200 Milligram, Two Times A Day		Aurobindo	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Rituximab			S	Intravenous drip	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701422	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR- APL-2020-020069		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Once A Day		Aurobindo	
	Effexor			S	Oral	150 Milligram, Daily		Not Reported	
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported	
	Acebutolol			C	Oral	400 Milligram, Once A Day		Not Reported	

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Amlodipine	C	Oral	10 Milligram, Once A Day	Not Reported
Clomipramine Hydrochloride	C	Oral	150 Milligram, 1 Month	Not Reported
Enoxaparin	C	Subcutaneous	4000 International Unit, Daily	Not Reported
Hydrochlorothiazide	C	Oral	25 Milligram, Once A Day	Not Reported
Macrogol 4000	C	Oral	2 Dosage Form, Daily	Not Reported
Nicardipine Hydrochloride	C	Oral	60 Milligram, Daily	Not Reported
Oxazepam	C	Oral	100 Milligram, Once A Day	Not Reported
Zopiclone	C	Oral	7.5 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701432	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020070		59 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Once A Day		Aurobindo
	Loxapine			S	Oral	155 Milligram, Once A Day		Not Reported
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Theralene			S	Oral	50 Milligram, Once A Day		Not Reported
	Akineton			C	Oral	4 Milligram		Not Reported
	Atorvastatine			C	Oral	40 Milligram, Once A Day		Not Reported
	Diazepam			C	Oral	10 Milligram, Once A Day		Not Reported
	Ezetimibe			C	Oral	10 Milligram, Once A Day		Not Reported
	Kardegic			C	Oral	75 Milligram, Once A Day		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Nebivolol			C	Oral	7.5 Milligram, Once A Day		Not Reported
	Nicopatch			C	Transdermal	7 Milligram, Once A Day		Not Reported
	Nicotine			C	Oral	12 Milligram, Once A Day		Not Reported
	Paracetamol			C	Oral	1 Gram, Once A Day		Not Reported
	Ramipril			C	Oral	1.25 Milligram, Once A Day		Not Reported

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Zopiclone			C	Oral	7.5 Milligram, Once A Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17702414	EXPEDITED (15-DAY)		HO, LT, OT	ES-SA-2020SA105860		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Thrombocytopenia	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S				Sanofi	
	Metamizole Salt Not Specified			S	Intravenous (not otherwise specified)	2 G, Q8h		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17702747	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-031352			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematous; Wound	Orencia			S	Subcutaneous			Bristol Myers Squibb	
	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	

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	Methotrexate	S	Oral	Unk		Not Reported
	Methotrexate	S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole	S	Unknown			Not Reported
	Prednisone	S	Unknown			Not Reported
	Remicade	S	Intravenous (not otherwise specified)			Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid		Not Reported
	Tofacitinib Citrate	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17702855	EXPEDITED (15-DAY)			CA-SA-2020SA102454			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased; Pregnancy	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	, 20-12.5 Mg;Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G		Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg		Sanofi

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17702988	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226290		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Aziticromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Compridos Recubiertos, 30 Compridos			S	Other	400 Milligram Daily; Route Of Administration: Sng		Not Reported
	Dolquine 200 Mg Compridos Recubiertos, 30 Compridos			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703170	EXPEDITED (15-DAY)		OT	GB-ALKEM LABORATORIES LIMITED-GB-ALKEM- 2020-01206			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Infection; Respiratory Tract Infection; Secondary Immunodeficiency; Urinary Tract Infection	Mycophenolate Mofetil			S	Unknown	Unk		Alkem	
	Mycophenolate Mofetil			S				Alkem	
	Azathioprine			S	Unknown	Unk		Alkem	
	Azathioprine			S				Alkem	
	Hydroxychloroquine			S		Unk		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703204	EXPEDITED (15-DAY)		OT	DE-HIKMA PHARMACEUTICALS USA INC.-DE-H14001- 20-511		42 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis; Erythema Nodosum; Herpes Dermatitis; Herpes Simplex; Immune Reconstitution Inflammatory Syndrome; Lymphoedema; Mass; Nodule; Panniculitis; Papilloma Viral Infection; Periorbital Oedema; Periorbital Swelling	Ceftriaxone			S	Unknown			Hikma	
	Ceftriaxone Sodium			S	Unknown			Not Reported	
	Streptomycin			S	Unknown			Not Reported	
	Prednisone			S	Unknown	()		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Cotrimoxazole			S	Unknown			Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported	
	Doxycycline			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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Azathioprine	S	Unknown	Not Reported
Acyclovir	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703265	EXPEDITED (15-DAY)	DE		ES-TEVA-2020-ES-1226288		65 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiogenic Shock; Drug Interaction;	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
Tachyarrhythmia	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703315	EXPEDITED (15-DAY)	OT		MX-ADVANSZ PHARMA-202004003552			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Sjogren'S Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703318	EXPEDITED (15-DAY)	DE		MX-ADVANSZ PHARMA-202004002571			Unknown	MEX

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atypical Pneumonia; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17703402	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020221		75 YR	Female	FRA

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

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Pulmonary Embolism	Paracetamol	S	Oral	4 Gram, Once A Day	Aurobindo
	Nefopam Hydrochloride	S	Oral	80 Milligram, Once A Day	Not Reported
	Augmentin	S	Intravenous (not otherwise specified)	3 Gram, Once A Day	Not Reported
	Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
	Amlor	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Colchimax (Colchicine/Papaver Somniferum Powder/Tiemonium Methylsulphate)	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Arimidex	S	Oral	1 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703409	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020223		66 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Aurobindo
	Plaquenil			S	Oral			Not Reported
	Zithromac			S	Oral	500 Milligram, Once A Day		Not Reported
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703414	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020196		81 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Condition Aggravated	Amoxicillin+Clavulanic Acid			S	Oral	1 Comp/8h		Aurobindo
	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Metronidazole			S	Oral	Unk		Aurobindo
	Dolquine			S	Oral	200 Milligram, Once A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703479	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3376441-00		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703559	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004003551			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Multiple Organ Dysfunction Syndrome; Off Label Use; Paralysis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703593	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004003545			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neoplasm Malignant; Papilloma Viral Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703666	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226209		95 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sudden Death	Quetiapina (1136a)			S	Oral	25 Mg		Teva	
	Levofloxacin (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva	

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	Hidroxiclороquina Sulfato (2143su)	S	Oral	200 Mg	Teva
	Risperidona (7201a)	S	Oral	1 Mg	Actavis
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S	Oral	2 Dosage Forms	Not Reported
	Losartan (7157a)	C	Oral	50 Mg	Not Reported
	Clindamicina Hidrocloruro (616ch)	C	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Lorazepam (1864a)	C	Oral	1 Mg	Not Reported
	Furosemida (1615a)	C	Oral	40 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703680	EXPEDITED (15-DAY)		OT	FI-ADVANSZ PHARMA-E2B_00008842			Unknown	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lymphopenia; Thrombocytopenia	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703729	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004003540			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chemotherapy	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703911	EXPEDITED (15-DAY)		HO	FR-ADVANSZ PHARMA-202004003504			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Disease Progression;	Hydroxychloroquine			S	Oral	200 Mg, (Film Coated Tablet)		Concordia

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Lymphopenia	Repaglinide	C	Unk	Not Reported
	Metformin	C	Unk	Not Reported
	Glimepiride	C	Unk	Not Reported
	Bisoprolol	C	Unk	Not Reported
	Perindopril	C	Unk	Not Reported
	Kardegic	C	Unk	Not Reported
	Levocetirizine	C	Unk	Not Reported
	Finasteride	C	Unk	Not Reported
	Pregabalin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17704031	DIRECT	Y	DE			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronavirus Infection	Hydroxychloroquine 400 Mg			S	Oral			Not Reported	
	Hydroxychloroquine 200 Mg			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17704205	EXPEDITED (15-DAY)		HO, OT	LT-ADVANS PHARMA-GSH201609-004911			Unknown	LTU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Body Temperature Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Enzyme Increased; Inflammatory Marker Increased; Rash Maculo-Papular	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Sulfasalazine			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17704214	EXPEDITED (15-DAY)		OT	CA-ADVANS PHARMA-202004003538			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Drug Ineffective; Drug Intolerance	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Leflunomide			S	Unknown	20 Mg		Not Reported
	Arava			S	Unknown	10 Mg		Not Reported
	Kevzara			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz Xr			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Pregabalin			C		Unk		Not Reported
	Vitamin B12 [Vitamin B12 Nos]			C		Unk		Not Reported
	Salazopyrin			C		Unk		Not Reported
	Codeine			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported
	Cortisone			C		Unk		Not Reported
	Dexilant			C		Unk		Not Reported
	Vitamin D [Vitamin D Nos]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17704217	EXPEDITED (15-DAY)		OT	CA-ADVANS PHARMA-202004003541			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Neuropathy Peripheral	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	1000 Mg, Bid		Concordia

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Orencia	S	Unknown	Unk	Not Reported
Losec	C			Not Reported
Clopidogrel	C		Unk	Not Reported
Rosuvastatin	C			Not Reported
Perindopril	C			Not Reported
Nitrospray	C			Not Reported
Methotrexate	C		Unk	Not Reported
Sulfasalazine	C			Not Reported
Amlodipine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17704377	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-01788		51 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Ototoxicity	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin	
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported	
	Prednisolone			C	Unknown	5 Milligram, Qd (Gradually Tapered)		Not Reported	
	Prednisolone			C	Unknown	10 Milligram, Qd (Dose Increased)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705063	NON-EXPEDITED			US-PFIZER INC- 2020159965		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Sulfasalazine			S		Unk		Pfizer	
	Humira			S		Unk		Not Reported	
	Hydroxychloroquine			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705271	EXPEDITED (15-DAY)		DE	ES-JNJFOC- 20200419053		95 YR	Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Risperdal			S	Oral			Janssen
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported
	Quetiapine			S	Oral			Not Reported
	Hidroxiclороquina Sulfato			S	Oral			Not Reported
	Kaletra			S	Oral	200/50 Mg		Not Reported
	Lorazepam			C	Oral			Not Reported
	Furosemida /00032601/			C	Oral			Not Reported
	Losartan			C	Oral			Not Reported
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705322	DIRECT		DE, HO			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Dysfunction; Cardio-Respiratory Arrest; Fall; Hallucination, Visual; Pulmonary Hypertension	Hydroxychloroquine			S	Oral	Quantity:1 Tablet(S);		Not Reported
	Triamcinolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705467	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100979		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Red	Hydroxychloroquine Sulfate			S				Sanofi
	Sulfasalazine			S				Not Reported
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Azathioprine			S				Not Reported

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

Blood Cell Sedimentation Rate Abnormal; Synovitis	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg, Solution Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	750 Mg	Not Reported
	Rituximab	S	Intravenous drip	2000 Mg	Not Reported
	Xeljanz	S			Not Reported
	Xeljanz	S	Oral	50 Mg, Bid (2 Every 1 Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705685	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2020162444		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Sudden Death	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705686	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162461		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Other	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported	
	Primperan			S	Intravenous drip	30 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705727	EXPEDITED (15-DAY)		HO	CA-SAOL THERAPEUTICS-2020SAO00108			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; C-Reactive Protein	Rho D Immune Globulin			S				Saol Therapeutics	
	Actemra			S	Intravenous (not	8.0 Mg/Kg, 1x/Month		Not Reported	

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Abnormal; Condition			otherwise specified)		
Aggravated; Drug	Arava	S		20 Mg	Not Reported
Hypersensitivity; Drug	Benzalkonium Chloride	S			Not Reported
Ineffective; Drug	Benzalkonium Chloride/	S			Not Reported
Intolerance;	Diphenhydramine Hydrochloride/				
Gastrointestinal Toxicity;	Phenylephrine Hy				
Hepatotoxicity; Infection;	Boric Acid	S			Not Reported
Joint Injury; Joint Stiffness;	Cimzia	S	Subcutaneous		Not Reported
Joint Swelling;	Disodium Edetate	S			Not Reported
Musculoskeletal Pain;	Enbrel	S	Subcutaneous	40 Mg, 1x/Week	Not Reported
Musculoskeletal Stiffness;	Gold	S			Not Reported
Neoplasm Malignant; Pain	Humira	S	Subcutaneous	40 Mg	Not Reported
In Extremity; Pulmonary	Hydroxychloroquine	S			Not Reported
Toxicity; Therapeutic	Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Product Effect Incomplete;	Methotrexate	S	Oral	15 Mg, 1x/Week	Not Reported
Therapy Non-Responder;	Methotrexate	S	Subcutaneous		Not Reported
Treatment Failure	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phenylephrine Hydrochloride	S			Not Reported
	Rituximab	S			Not Reported
	Simponi	S			Not Reported
	Sodium Borate	S			Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S		10 Mg, 2x/Week	Not Reported
	Tofacitinib Citrate	S		5 Mg, 2x/Week	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	5 Mg, 2x/Week	Not Reported
	Celebrex	C	Oral	400 Mg	Not Reported
	Ibuprofen	C	Oral	400 Mg	Not Reported
	Lipitor	C	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705848	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-		73 YR	Female	ESP

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3376750-00

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Ageusia; Anosmia; Condition Aggravated; Nausea; Off Label Use; Oxygen Saturation; Productive Cough; Pyrexia	Kaletra			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Heparin			C		Prophylactic Dose		Not Reported
	Tocilizumab			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705929	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1226300		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycine Anhydre			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lovenox			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705944	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226289		28 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram Daily;		Not Reported

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Ceftriaxona (501a)	S	otherwise specified)	Not Reported
Paracetamol (12a)	S	Intravenous (not otherwise specified) 1 Gram Every 8 Hours	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706122	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032305			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Apo-Folic Acid			S	Unknown	Unk		Not Reported	
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported	
	Apo-Prednisone			S	Unknown	Unk		Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Cortisone Acetate			S	Unknown	Unk		Not Reported	
	Cortisone Acetate			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Folic Acid			S	Unknown	5 Milligram		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	

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

Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706318	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162376			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Off Label Use; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706431	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226597		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tofacitinib Citrate			S	Oral	10 Milligram Daily;		Not Reported	
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported	

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Aspirin [Acetylsalicylic Acid]	C	Unknown	Not Reported
Cimzia Single-Use Prefilled Syringe	C	Subcutaneous	Not Reported
Cymbalta	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706432	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226715			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706435	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226417		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia;	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr

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Rash; Toxicity To Various Agents; Visual Impairment	Actemra	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral	1 Milligram Daily;	Not Reported
	Xeljanz	C	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706545	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226712			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	5 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706575	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226588		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Alendronate Codeine Actemra Actemra Etanercept Etanercept Humira Hydroxychloroquine Sulfate Myochrysine Orencia Remicade Rituximab Sulfasalazine	S S S S S S S S S S S S S S S S S S S S S	Oral Unknown Unknown Unknown Subcutaneous Unknown Subcutaneous Oral Unknown Unknown Unknown Unknown Unknown Subcutaneous Oral Unknown Unknown Unknown Unknown Unknown Unknown	Barr Barr Barr Barr Barr Barr Barr Actavis Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706578	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226794			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Leflunomide			S	Unknown			Barr	
Arthralgia; Diarrhoea;	Leflunomide			S	Unknown			Barr	
Drug Hypersensitivity;	Methotrexate			S	Subcutaneous			Barr	
Infection; Joint Swelling;	Methotrexate			S	Subcutaneous			Barr	
Lower Respiratory Tract Infection; Nausea;									

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Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous		Barr
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown	100 Milligram Daily;	Not Reported
	Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Vitamin D3	C			Not Reported
	Imuran [Azathioprine]	C			Not Reported
	Gold	C			Not Reported
	Arthrotec	C	Unknown	100 Milligram Daily;	Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706582	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226586		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Asa			C	Unknown			Not Reported	
	Clonazepam			C	Oral			Not Reported	
	Desipramine			C	Oral			Not Reported	
	Gabapentin			C	Oral			Not Reported	
	Nitroglycerin			C	Unknown			Not Reported	
	Rosuvastatin Calcium			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706588	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226758		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr	
	Naproxen Sodium			S	Unknown			Teva	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Folic Acid	C		Not Reported
Methotrexate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706589	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1226786			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Off Label Use; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Leflunomide			S	Unknown			Barr
	Leflunomide			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Ilaris Single-Use Vial			S	Intravenous (not otherwise specified)			Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706590	EXPEDITED (15-DAY)	HO		CA-TEVA-2020-CA-1226708		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706609	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226204		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Unknown			Barr	
	Alendronate Sodium			S	Unknown			Actavis	
	Codeine			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Myochrysine			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Unknown	2000 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Ciclosporin			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706648	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226631			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	

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

Apo-Prednisone	S	Unknown	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Reactine (Cetirizine)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706659	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226499			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Mood Altered	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706688	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226489			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Headache; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral	2.5 Milligram Daily;		Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Pantoprazole			C	Oral	40 Milligram Daily;		Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Tenofovir Disoproxil			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Zopiclone			C	Unknown	7.5 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706692	EXPEDITED (15-DAY)		OT	NVSC2020DE069507		58 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Acute Febrile Neutrophilic Dermatitis; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Ramipril	S	Oral	Unk	Not Reported
	Amlodipine	S	Unknown	Unk	Novartis
	Esomeprazole	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Boswellia Serrata Extract	S	Unknown	Unk	Not Reported
	Thyroxine	C	Unknown		Not Reported
	Levothyroxine Sodium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706698	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226415		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Aspirin [Acetylsalicylic Acid]			C				Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706704	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226800		61 YR	Female	CAN

FDA Adverse Event Reporting System

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706706	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226401			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Joint Swelling; Liver Injury	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706708	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226422			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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

Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Neutropenia; White Blood Cell Count Decreased	Leflunomide	S	Unknown		Barr
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Enbrel	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706711	EXPEDITED (15-DAY)	DE, LT		NVSC2020CA108434		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Ilaris			S	Subcutaneous	Unk		Novartis
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Ilaris			S				Novartis
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Hydroxychloroquine			S	Unknown	Unk		Not Reported
Drug Hypersensitivity;	Hydroxychloroquine			S				Not Reported
Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling;	Sulfasalazine			S	Unknown	500 Mg		Not Reported
Myocardial Infarction; Off Label Use; Pain;	Sulfasalazine			S				Not Reported
Photosensitivity Reaction;	Methotrexate Sodium			S	Unknown	Unk		Not Reported
Pulmonary Embolism;	Methotrexate Sodium			S				Not Reported
Pulmonary Thrombosis;	Methotrexate			S	Unknown			Not Reported
Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Rituximab			S	Unknown	Unk		Not Reported
Sepsis; Stomatitis;	Rituximab			S				Not Reported
Terminal State;	Leflunomide			S	Unknown			Not Reported
Thrombosis; Urticaria	Leflunomide			S				Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported

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

Gold	S	Unknown	Unk	Not Reported
Gold	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S			Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Oxycodone	S	Unknown	10 Mg	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S			Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S			Not Reported
Xeljanz	S	Oral	2 Df, Qd	Not Reported
Leflunomida	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706712	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226575		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Clostridium Difficile Infection; Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Myochrysine			S	Unknown			Not Reported	

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

Enbrel	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Humira	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	20 Milligram Daily;
Orencia	C	Unknown	Not Reported
Orencia	C	Unknown	Not Reported
Remicade	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706716	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226199		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706718	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226485		41 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Nodule	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706719	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226393			Female	CAN

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706723	EXPEDITED (15-DAY)		LT	NVSC2020CA108426		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C- Reactive Protein Increased;	Ilaris			S	Subcutaneous	Unk		Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported

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

Contraindicated Product	Methotrexate Sodium	S	Unknown	Unk	Not Reported
Administered; Deep Vein	Minocycline	S	Unknown	Unk	Not Reported
Thrombosis; Diverticulitis;	Minocycline Hydrochloride	S	Unknown		Not Reported
Drug Hypersensitivity;	Oxycodone	S	Unknown	10.0 Mg	Not Reported
Drug Ineffective; Drug	Leflunomide	S	Unknown	Unk	Not Reported
Intolerance; Feeling	Leflunomide	S			Not Reported
Abnormal; Haemoglobin	Actemra	S	Unknown	Unk	Not Reported
Decreased; Herpes	Actemra	S			Not Reported
Zoster; Intentional Product	Anakinra	S	Unknown		Not Reported
Use Issue; Interstitial Lung	Anakinra	S			Not Reported
Disease; Joint Swelling;	Arava	S	Unknown	Unk	Not Reported
Myocardial Infarction; Off	Arava	S			Not Reported
Label Use; Pain;	Enbrel	S	Subcutaneous	Unk	Not Reported
Photosensitivity Reaction;	Enbrel	S			Not Reported
Pulmonary Embolism;	Gold	S	Unknown	Unk	Not Reported
Pulmonary Thrombosis;	Humira	S	Unknown	Unk	Not Reported
Red Blood Cell	Humira	S	Subcutaneous	Unk	Not Reported
Sedimentation Rate	Hidroxicloroquina	S	Unknown		Not Reported
Increased; Renal Failure;	Hidroxicloroquina	S			Not Reported
Sepsis; Stomatitis;	Marijuana	S	Unknown	Unk	Not Reported
Terminal State;	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Thrombosis; Urticaria	Orencia	S			Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Rituximab	S			Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sodium Aurothiomalate	S			Not Reported

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

Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral	Unk (2 Every 1 Days)	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706744	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226225			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased;	Leflunomide			S	Unknown			Barr
Contraindicated Product Administered; Diarrhoea;	Leflunomide			S	Unknown			Barr
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Transaminases Increased	Methotrexate			S	Unknown			Barr
	Cosentyx			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706821	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226617		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Back Pain; Crying; Depression; Fatigue; Joint Stiffness; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling; Swelling; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg		Barr
	Methotrexate			S	Unknown	12.5 Mg, 4 Every 1 Week		Barr
	Methotrexate			S	Unknown	20 Mg, 4 Every 1 Week		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral 2 Gram Daily;	Not Reported
	Rituxan	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral 10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706824	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226496		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Leflunomide			S	Unknown	200 Milligram Daily;		Barr	
	Acetaminophen			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Acetaminophen			S	Unknown			Not Reported	
	Arava			S	Oral	20 Milligram Daily;		Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	

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

	Sulfasalazine	S	Oral	Not Reported
	Tylenol	S	Unknown	Not Reported
	Hydromorphone Hydrochloride	C		Not Reported
	Meloxicam	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706884	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226629		55 YR	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Toxicity To Various Agents; Visual Impairment	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral	1 Gram Daily;		Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706888	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226486		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis;	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	

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

Scar; Vomiting	Sulfasalazine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Aspirin[Acetylsalicylic Acid]	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706960	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226817			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intestinal Perforation; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706962	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227023			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide	S	Unknown		Barr
	Naproxen	S	Unknown		Teva
	Prednisone	S	Unknown		Actavis
	Actemra	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Folic Acid	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706969	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226569			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706970	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226578		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Oral			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Alendronate			S	Unknown			Actavis	
	Codeine			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip	2000 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Ciclosporin			C				Not Reported	
	Prednisone			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707004	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226718		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Alendronic Acid			S	Unknown			Actavis	
	Codeine			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip	2000 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Ciclosporin			C	Unknown	150 Milligram Daily;		Not Reported	

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Prednisone			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707009	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226580			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthralgia; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Bifidobacterium Bifidum			C	Unknown			Not Reported	
	Loperamide			C	Oral			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707545	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226576			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707742	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226778		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash	Leflunomide			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone Acetate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707753	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1225340			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthralgia; Rheumatoid Arthritis	Cyclobenzaprine Hcl 5 Mg Tablet	S	Unknown		Actavis
	Xeljanz	S	Oral	10 Milligram Daily; 60/Btl	Not Reported
	Narcan 4 Mg Spray	S	Unknown	Spray	Not Reported
	Plaquenil 200 Mg Tablet	S	Unknown		Not Reported
	Hydrochlorothiazide 25 Mg Tablets	S	Unknown		Not Reported
	Wellbutrin XI Tab Er	S	Unknown	150 Milligram Daily; Er	Not Reported
	Wellbutrin XI Tab Er	S	Unknown	300 Milligram Daily; Er	Not Reported
	Prednisone 10 Mg Tablet	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707828	EXPEDITED (15-DAY)		HO	ES-009507513-2004ESP006461		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Ertapenem Sodium			S	Intravenous (not otherwise specified)	1 G Day		Merck	
	Piperacillin Sodium (+) Tazobactam Sodium			S	Intravenous (not otherwise specified)	C/24 H		Not Reported	
	Azithromycin			S	Oral	500 Mg Per Day		Not Reported	
	Dolquine			S	Oral	400 Mg Per Day		Not Reported	
	Dolquine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707836	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226792			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Leukopenia; Neutropenia; Therapeutic Response Decreased	Leflunomide			S	Oral	20 Milligram Daily;		Barr	
	Methotrexate			S	Unknown			Barr	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707886	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226781		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Leflunomide			S	Unknown			Barr	
	Naproxen Sodium			S	Unknown			Teva	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17710887	DIRECT		DE			50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Myocardial Infarction	Hydroxychloroquine	Y		S				Not Reported	
	Biotin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	14994173	EXPEDITED (15-DAY)		OT	US-ACCORD-067914		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Retinal Toxicity; Visual Field Defect	Anastrozole			S				Accord	
	Docetaxel			S		Four 21-Day Cycles		Not Reported	
	Hydroxychloroquine			S		Hcq Daily Dose: 7.01		Not Reported	

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Cyclophosphamide/Cyclophosphamide Monohydrate			S		Mg/Kg And Total Cumulative Dose 402 G			21-Day Cycles		Not Reported	
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25-Apr-2020	15611218	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-091251		15 YR	Female	ITA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Acute Kidney Injury; Drug Intolerance;	Mycophenolic Acid			S				Accord			
Gastrointestinal Disorder;	Tacrolimus			S				Accord			
Haematuria; Headache;	Hydroxychloroquine			S				Not Reported			
Hypertransaminasaemia;	Rituximab			C				Not Reported			
Nausea; Pneumonia;	Cyclophosphamide/Cyclophosphamide Monohydrate			C		Pulse		Not Reported			
Proteinuria; Pyrexia;	Methylprednisolone			C				Not Reported			
Respiratory Symptom	Amphotericin B/Amphotericin B/Liposome			C				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
25-Apr-2020	16739695	EXPEDITED (15-DAY)		OT	DE-ACCORD-152822			Female	DEU		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Arthralgia; Arthropathy;	Ramipril			S	Oral	1 Df Bid (1-0-1), 2x/Day		Accord			
Ligament Sprain;	Pregabalin			S	Unknown	1 Df, Tid (1-1-1)		Not Reported			
Nasopharyngitis; Oedema	Sildenafil/Sildenafil Citrate			S	Unknown			Not Reported			
Peripheral; Pain In	Ambrisentan			S				Not Reported			
Extremity; Paraesthesia;	Quensyl			S	Unknown	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg Bid		Not Reported			
Pulmonary Hypertension;	Eliquis			S	Unknown	1 Df, Bid (1-0-1), 5 Mg Per Day, 2.5 Mg Bid,		Not Reported			
Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Roactemra			S		162 Mg, Qw		Not Reported			
	Spasmolyt			S		15 Mg, Qd (1-0-0),Also Received 30 Mg (0 -0 -1)		Not Reported			

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Omeprazole	S	Oral	1 Df, Bid (1-0-1), 40 Mg Per Day, 20 Mg, Bid	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Lyrica	S	Unknown	100 Mg, Tid	Not Reported
Spasmolyt	S		30 Mg (0 -0 -1)	Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Ramipril	S	Unknown		Accord
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1)	Not Reported
Volibris	S	Oral		Not Reported
Trospium Chloride	S		30 Mg (0 -0 -1)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17678870	EXPEDITED (15-DAY)		LT, OT	FR-ADVANS PHARMA-202004002849			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Coma; Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd, Film Coated Tablet		Concordia	
	Hydroxychloroquine			S	Oral	Unk		Concordia	
	Midazolam			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Morphine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17707971	EXPEDITED (15-DAY)		OT	MX-ADVANS PHARMA-202004003553			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Eye Disorder; Off Label Use; Product Dose Omission	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	

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25-Apr-2020	17708013	EXPEDITED (15-DAY)		OT	IT-ADVANSZ PHARMA-GSH201610-005089			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Dilatation Atrial	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia	
	Methotrexate			S	Unknown	7.5 Mg Every 10 Days		Not Reported	
	Methotrexate			S		Reduction In The Dose Of Methotrexate 7.5 Mg Every 10 Days		Not Reported	
	Certolizumab Pegol			S	Unknown	200 Mg Every Other Week		Not Reported	
	Certolizumab Pegol			S	Unknown	200 Mg Every Other Week		Not Reported	
	Bromazepam			C				Not Reported	
	Bromazepam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17708019	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-MAPI_00011385			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Function Test Abnormal; Cardiotoxicity; Ejection Fraction Decreased; Product Use In Unapproved Indication; Sinus Tachycardia; Tachycardia; Ventricular Hypokinesia	Hydroxychloroquine			S	Unknown	600 Mg, Qd		Concordia	
	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Doxycycline			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17708183	EXPEDITED (15-DAY)		DS, OT	US-ADVANSZ PHARMA-202004004057			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness	Hydroxychloroquine			S		Unk		Concordia	

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25-Apr-2020	17708184	EXPEDITED (15-DAY)		DS, OT	US-ADVANSZ PHARMA-202004003665			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17574299	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-GSH201806-002062			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Off Label Use; Retinal Toxicity; Toxicity To Various Agents	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	7.01 Mg/Kg, Qd (Total Cumulative Dose 402 G)		Concordia	
	Cyclophosphamide			S	Unknown	21-Day Cycles		Not Reported	
	Docetaxel			S	Unknown	21-Day Cycles		Not Reported	
	Anastrozole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17708342	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA108440			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Ilaris			S	Subcutaneous			Novartis	
	Ilaris			S				Novartis	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S				Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Methotrexate Sodium			S				Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S				Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S				Not Reported	

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Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Thrombosis; Urticaria	Minocycline	S	Unknown		Not Reported
	Minocycline Hydrochloride	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg	Not Reported
	Sulfasalazine	S			Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Anakinra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S			Not Reported
	Arava	S	Unknown		Not Reported
	Arava	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S			Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S			Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S			Not Reported
	Marijuana	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S			Not Reported
	Oxycodone	S	Unknown	10 Mg	Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S			Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sodium Aurothiomalate	S			Not Reported
	Xeljanz	S	Oral		Not Reported

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26-Apr-2020	17708442	EXPEDITED (15-DAY)		OT	NVSC2020CA111350			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Hypothyroidism; Obesity; Osteoarthritis; Osteopenia; Synovitis; Therapeutic Product Effect Incomplete	Cosentyx			S	Unknown	Unk Unk, Unknown		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	10 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported
	N-(3-Chloroallyl)Hexaminium Chloride			S	Unknown	Unk		Not Reported
	Penicillin G			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	50 Mg, Qmo		Not Reported
	Stelera			S	Unknown	Unk, 1 Every 8 Weeks		Not Reported
	Stelera			S	Subcutaneous	Unk		Not Reported
	Cetirizine			C	Unknown	10 Mg, Bid		Not Reported
	Enbrel			C	Unknown	50 Mg, Qw		Not Reported
	Lasix			C	Unknown	40 Mg, Qmo		Not Reported
	Montelukast			C	Unknown	10 Mg, Qd		Not Reported
	Synthroid			C	Unknown	75 Mg, Qd		Not Reported
	Terbutaline Sulfate			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17708667	EXPEDITED (15-DAY)		OT	NVSC2020CH106927		33 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Product Use In Unapproved Indication; Therapy Non-Responder	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Novartis
	Methotrexate			S	Unknown	Unk Ukn		Not Reported
	Azathioprine			S	Unknown	Unk Ukn		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Hydroxychloroquine	S	Unknown	Unk Ukn			Not Reported	
		Infliximab	S	Unknown	Unk Ukn			Not Reported	
		Prednisone	S	Unknown	20 Mg, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17709300	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2020-020616			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S				Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Plaquenil			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17711723	DIRECT					28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tachycardia	Hydroxychloroquine	Y		S	Oral			Not Reported	
	Propranolol			C				Not Reported	
	Valium			C				Not Reported	
	Prilosec			C				Not Reported	
	Pristiq			C				Not Reported	
	Norethidrone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	13058853	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015743		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush;	Leflunomide			S	Unknown	Unk		Apotex	
	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Actemra			S	Unknown	8 Mg, Unk		Not Reported	

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Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Humira	S	Unknown	40 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Rituximab;Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Arava	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Elavil /00002202/	C	Unknown	Unk	Not Reported
	Hydrochlorothiazide	C	Unknown	Unk	Not Reported
	Imitrex /01044801/	C	Unknown	Unk	Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Premarin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Tenormin	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Sumatriptan Succinate	C	Unknown	Unk	Not Reported
	Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
	Amitriptyline	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	13188059	EXPEDITED (15-DAY)		HO, OT	CA-GLENMARK PHARMACEUTICALS- 2017GMK026159			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction;	Gabapentin			S	Oral	100 Mg, Bid		Glenmark
Adverse Event; Adverse	Gabapentin			S	Unknown	100 Mg, Bid		Glenmark
Reaction; Arthralgia;	Celebrex			S	Oral	Unk		Not Reported
Arthropathy; Blood	Celebrex			S	Unknown	Unk		Not Reported
Creatinine Increased;	Celebrex			S	Oral	Unk		Not Reported
Blood Magnesium	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
Increased; Blood	Enbrel			S	Subcutaneous	50 Mg, Qw (Solution		Not Reported
Potassium Increased;	Enbrel			S	Subcutaneous	Subcutaneous)		Not Reported
Bone Cyst;	Enbrel			S	Subcutaneous	50 Milligram, Qw		Not Reported
Contraindicated Product	Fentanyl			S	Unknown	Unk		Not Reported
Administered; Crohn'S	Fentanyl			S	Unknown	Unk		Not Reported
Disease; Cyst; Deafness	Fentanyl Citrate			S	Epidural	Unk		Not Reported
Neurosensory; Deformity;	Fentanyl Matrix			S	Unknown	Unk		Not Reported
Diarrhoea; Drug	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
Hypersensitivity; Drug	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
Ineffective; Drug	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
Intolerance; Dry Eye;	Methotrexate			S	Unknown	Unk		Not Reported
Epigastric Discomfort;	Methotrexate			S	Subcutaneous	1 Df, Qw		Not Reported
Exostosis; Fatigue;	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
Gastrointestinal Disorder;	Methotrexate			S	Subcutaneous	Unk, Qw		Not Reported
Hospitalisation;	Methotrexate			S	Subcutaneous	1 Dosage Form, Qw		Not Reported
Hypersensitivity; Infection;	Hydroxychloroquine			S	Unknown	Unk		Not Reported
Intentional Product Use	Hydroxychloroquine			S	Unknown	400 Mg, Od		Not Reported
Issue; Joint Swelling;	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Od, 1 Every 1		Not Reported
Mobility Decreased;	Hydroxychloroquine Sulfate			S	Unknown	Day		Not Reported
Musculoskeletal Stiffness;	Arava			S	Oral	20 Mg, Od		Not Reported
Myocardial Infarction;	Arava			S	Unknown	Unk		Not Reported
Nausea; Off Label Use;								
Osteoarthritis; Osteopenia;								
Osteosclerosis; Pain; Pain								
In Extremity; Pleural								
Fibrosis; Pleural								
Thickening; Presbycusis;								
Renal Impairment;								
Rheumatoid Arthritis; Skin								
Lesion; Sleep Disorder;								
Therapeutic Product Effect								
Decreased; Treatment								
Failure								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Oral	20 Mg, Od 1 Every 1 Day	Not Reported
Apo Gabapentin	S	Oral	100 Mg, Bid (2 Every 1 Day)	Not Reported
Apo Gabapentin	S	Unknown	Unk	Not Reported
Apo Celecoxib	S	Oral	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
Nortriptyline Hydrochloride	S	Oral	10 Milligram, 1 Every 1 Hour	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Once Every 3 Weeks (Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	Unk(Solution Intramuscular)	Not Reported
Myochrysine	S	Intramuscular	Unk(Solution Intramuscular); Once Every 3 Weeks	Not Reported
Myochrysine	S	Intramuscular	50 Mg, 1 Every 3 Weeks	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Weeks	Not Reported
Orencia	S	Subcutaneous	Unk, Qw, 1 Every 1 Week	Not Reported
Orencia	S	Subcutaneous	1 Dosage Form, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	750 Milligram, 1 Every 4 Week	Not Reported
Orencia	S	Vaginal	750 Milligram, 1 Every 1 Month	Not Reported
Oxycontin	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Oral	500 Mg, Qd	Not Reported
Sulfasalazine	S	Oral	2.5 Mg, Od, 1 Every 1 Day	Not Reported
Sulfasalazine	S	Oral	2.5 Gram, Od	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	468 Mg, Once Every 1 Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	488 Mg, Once Every 1 Month	Not Reported
Actemra	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk, Od	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Od	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk, 1 Every 1 Hour	Not Reported
Esomeprazole /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole /01479302/	C	Unknown	400 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Od	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Loperamide	C	Unknown	Unk	Not Reported

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Loperamide	C	Unknown	2.5 Milligram	Not Reported
Nasonex	C	Nasal	2 Df, Bid (Spray, Metered Dose)	Not Reported
Nasonex	C	Unknown	2 Df, Bid	Not Reported
Nasonex	C	Nasal	2 Df, Bid	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	5 Mg, Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Od	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Cyclical	Not Reported
Trazodone Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, 1 Every 1 Hour	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks (Intravenous Solution)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Once Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aclasta	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk (1 Every 2 Weeks)	Not Reported
Actonel	C	Unknown	36 Mg, Qw	Not Reported
Actonel	C	Unknown	Unk	Not Reported
Actonel	C	Unknown	Unk, Od	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Od	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D /00107901/	C	Unknown	400 Df, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	Unk	Not Reported
Multivitamin /00097801/	C	Unknown	Unk	Not Reported
Omega 3 /01333901/	C	Unknown	1200 Mg, Bid	Not Reported
Omega 3 /01333901/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Biotin W/Calcium Pantothenate/Colec/06004901/ Docosahexaenoic Acid	C	Unknown	Unk	Not Reported
Aclasta	C	Unknown	1 Df, Qd (1 Every 1 Day)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, 1 Every 1 Month	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	1200 Mg, Bid	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentaenoic Acid	C	Unknown	Unk, Od	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported

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Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Cyclical	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk, Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Gigabecquerel, 1 Evrey 1 Hour	Not Reported
Pantoprazole	C	Unknown	400 Mg, Od	Not Reported
Pantoprazole	C	Unknown	40 Mg, Od	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Perfenazine	C	Oral	10 Mg, Unk	Not Reported
Perfenazine	C	Unknown	40 Mg, Od, 1 Every 1 Day	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk, Od, 1 Every 1 Day	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Od	Not Reported
Fergon	C	Unknown	300 Mg, Od	Not Reported
Nortriptyline	C	Urethral	Unk	Not Reported

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Vitamin E /00110501/	C	Unknown	Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Omega-3 /01866101/	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride W/Perphenazine	C	Oral	Unk, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Lomotil /00034001/	C	Unknown	Unk	Not Reported
Lomotil /00034001/	C	Unknown	2.5 Milligram, Od	Not Reported
Actonel	C	Unknown	36 Mg, 1 Every 1 Week	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Od	Not Reported
Trazodone	C	Unknown	Unk	Not Reported
Diphenoxylate	C	Unknown	2.5 Mg, Od	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Unknown	Unk	Not Reported
Genteal /00445101/	C	Ophthalmic	Unk	Not Reported
Oxycodone Hydrochloride W/Oxycodone Terephtha Percocet /00867901/	C	Unknown	1 Df, Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Vitamin B 12	C	Unknown	Unk	Not Reported
Vitamin B12 Aaa	C	Unknown	Unk	Not Reported
Acetaminophen	C	Oral	1000 Mg, Od (1 Every 24 Hours)	Not Reported
Acetaminophen W/Oxycodone	C	Unknown	Unk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, 1 Every 1 Month	Not Reported
Aclasta	C	Unknown	480 Milligram, 1 Every 1	Not Reported

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Lomotil /00034001/	C	Unknown	Month	Not Reported
Vitamin B3	C	Unknown	Unk	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, 1 Every 1 Week (Qw)	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulf	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	15208961	EXPEDITED (15-DAY)		HO, OT	GR-ALLERGAN-1835963US			Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Raynaud'S Phenomenon; Renal Impairment; Scleroderma; Scleroderma Renal Crisis; Thrombocytopenia; Weight Decreased	Citalopram Hydrobromide	Unk		S	Unknown	Unk		Allergan
	Alprazolam			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q Week		Not Reported
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Hydroxychloroquine			S				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Folate			S	Unknown	5 Mg, Q Week		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Etanercept			S				Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Captopril			S	Unknown	Unk		Not Reported
	Captopril			S				Not Reported
	Valsartan			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	15396329	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180911207		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-	Remicade			S	Intravenous (not			Janssen

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Reactive Protein			otherwise specified)	
Abnormal; Condition	Simponi	S	Subcutaneous	Janssen
Aggravated;				
Contraindicated Product	Simponi	S		Janssen
Administered; Drug	Tylenol	S	Unknown	Johnson And Johnson
Ineffective; Drug	Paracetamol	S	Unknown	Johnson And Johnson
Intolerance; Fatigue; Gait	Paracetamol	S	Unknown	Johnson And Johnson
Disturbance; Joint				
Swelling; Loss Of	Arava	S	Oral	Not Reported
Personal Independence In	Arava	S	Unknown	Not Reported
Daily Activities; Malaise;				
Nephrolithiasis; Pain; Pain	Cimzia	S	Subcutaneous	Not Reported
In Extremity; Peripheral	Humira	S	Subcutaneous	Not Reported
Swelling; Red Blood Cell				
Sedimentation Rate	Orencia	S	Unknown	Not Reported
Increased; Rheumatoid	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Arthritis; Somnolence;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Visual Impairment	Plaquenil	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	W/Diphenhydramine			
	Hydrochloride			
	Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Actemra	S	Subcutaneous	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported

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Apo-Prednisone	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Tylenol W/Codeine No. 3	C	Unknown	Not Reported
Celebrex	C	Oral	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Codeine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	15493226	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP022036		59 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Amlodipine			S	Oral	5 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Asacol			S	Oral	800 Mg, Tid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, One Every 2		Not Reported

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			Weeks	
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	2.5 Mg, Q.Wk.	Not Reported
Methotrexate	S			Not Reported
Actemra	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Amlodipine Besilate	C	Unknown	Unk	Not Reported
Atacand Plus	C	Unknown	Unk	Not Reported
Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
Depo-Medrol	C	Intra-articular	Unk	Not Reported
Ferrous Gluconate	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
Zopiclone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	15567436	NON-EXPEDITED			US-PFIZER INC-2018432992		74 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Clindamycin			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	16646824	EXPEDITED (15-DAY)		HO, OT	PL-PFIZER INC-2019317440		35 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Sulfasalazine			S	Unknown	Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Encorton			S	Unknown	15 Mg, Qd (Every Day)		Not Reported
	Encorton			S	Unknown	10 Mg, Qd (Every Day)		Not Reported
	Plaquenil S			S		20 Mg, 1x/Day; Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Mg, Unk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Mg, Qw (Every Week)		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In Jan-2019)		Not Reported
	Insulin			C	Unknown	Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	16783255	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201805-001712			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Bloody Discharge; Drug	Hydroxychloroquine	S	Oral	400 Mg, Qd Tablet	Concordia
Hypersensitivity; Drug	Hydroxychloroquine	S	Unknown	Unk	Concordia
Intolerance; Fatigue;	Erythromycin	S	Unknown	Unk	Not Reported
Infection; International	Erythromycin	S	Unknown	Unk	Not Reported
Normalised Ratio	Erythromycin	S	Unknown	Unk	Not Reported
Fluctuation; Lyme	Erythromycin	S	Unknown	Unk	Not Reported
Disease; Nausea;	Erythromycin	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Erythromycin	S	Unknown	Unk	Not Reported
Incomplete; Vomiting	Erythromycin	S		Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Arthrotec	S	Intracardiac	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Ceclor	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	200 Mg, Qd	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk Subcutaneous Solution	Not Reported
	Humira	S	Subcutaneous	40 Mg; Subcutaneous Solution	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
	Lyrica	S	Unknown	Unk	Not Reported
	Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	1 Dosage Form, Weekly	Not Reported
	Metronidazole	S	Intravenous (not otherwise specified)	5 Mg	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metronidazole	S			Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Cefaclor	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Celecoxib	S	Oral	200 Mg	Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Apo-Bisoprolol	S	Unknown	Unk	Not Reported
Meperidine	S	Unknown	Unk	Not Reported
Levofloxacin	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Erythromycin Estolate	S	Unknown	Unk	Not Reported
Erythro Base	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	400 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	16944449	EXPEDITED (15-DAY)		HO	US-EMCURE PHARMACEUTICALS LTD-2018-EPL-0469		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hypokalaemia; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram		Emcure
	Hydroxychloroquine			S		4 Dosage Form		Not Reported
	Activated Charcoal			C	Oral	50 Gram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17168352	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019228928			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Exposure During Pregnancy; Fatigue; Glossodynia; Liver Injury; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline	
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline	
	Diclofenac Sodium			S	Unknown	Unk		Glaxosmithkline	
	Folic Acid			S	Unknown	1 Mg		Glaxosmithkline	
	Folic Acid			S	Unknown	1 Milligram		Glaxosmithkline	
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline	
	Desoximetasone			S	Unknown	Unk		Glaxosmithkline	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Certolizumab Pegol			S	Subcutaneous	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk, Solution		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Solution		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Solution		Not Reported	

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Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Glaxosmithkline
Quetiapine	C	Unknown	Unk	Glaxosmithkline
Ramipril	C	Unknown	Unk	Glaxosmithkline
Calcium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17182234	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1154329			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Leflunomide			S	Unknown			Barr	

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Anaphylactic Shock; Blood Test Abnormal; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Methotrexate	S	Unknown	Barr
	Otezla	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Doxepin Hydrochloride	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17298077	EXPEDITED (15-DAY)		OT	FR-ACCORD-168315		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acarodermatitis	Mycophenolic Acid			S	Unknown			Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Cyclophosphamide/Cyclophosphamide Monohydrate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17560623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567748		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Arthralgia; C-Reactive Protein Abnormal; Chest	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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Pain; Contraindicated	Mycophenolate Mofetil	S	Unknown	Not Reported
Product Administered;	Azathioprine	S	Unknown	Not Reported
Diarrhoea; Drug	Ciclosporin	S	Unknown	Not Reported
Hypersensitivity; Drug	Enbrel	S	Subcutaneous	Not Reported
Intolerance; Dyspnoea;	Gold	S	Unknown	Not Reported
Elbow Deformity; Fatigue;	Humira	S	Subcutaneous	Not Reported
Headache; Jaw Fracture;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Joint Swelling;	Methotrexate	S	Subcutaneous	Not Reported
Musculoskeletal Pain;	Orencia	S	Subcutaneous	Not Reported
Nausea; Neck Pain; Off	Penicillamine	S	Unknown	Not Reported
Label Use; Overlap	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Syndrome; Pain In	Simponi	S	Subcutaneous	Not Reported
Extremity; Pain In Jaw;	Amitriptyline Hydrochloride	C	Unknown	Not Reported
Proteinuria; Red Blood	Doxycycline	C	Unknown	Not Reported
Cell Sedimentation Rate	Prednisone	C	Unknown	Not Reported
Abnormal; Sle Arthritis;	Sulfasalazine	C	Unknown	Not Reported
Toxicity To Various	Tobramycin	C	Unknown	Not Reported
Agents; Treatment Failure;	Xeljanz	C	Oral	Not Reported
Vasculitis; Weight	Elavil [Amitriptyline Hydrochloride]	C		Not Reported
Decreased				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17584892	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020125649		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bartonella Test Positive;	Methotrexate Sodium			S		Unk		Pfizer	
Cat Scratch Disease;	Rituximab			S		Unk		Not Reported	
Device Dislocation;	Hydroxychloroquine			S		Unk		Not Reported	
Pneumonia									

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27-Apr-2020	17647567	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200403521			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Simponi			S	Subcutaneous			Janssen	
	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17659064	EXPEDITED (15-DAY)		DE, OT	TH-ROCHE-2577353		44 YR	Male	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Cerebral Haemorrhage; Injection Site Extravasation; Intentional Product Use Issue; Off Label Use; Proteinuria; Renal Failure	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Lopinavir			S	Unknown			Not Reported	
	Ritonavir			S	Unknown			Not Reported	
	Favipiravir			S	Unknown			Not Reported	
	Darunavir			S	Unknown			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Piperacillin			S	Unknown			Not Reported	
	Tazobactam			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Enoxaparin			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17666251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009862		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Cyclosporine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Xeljanz Xr			C	Unknown	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17666598	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201712-006550			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia
	Arava			S	Oral	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Weekly		Not Reported
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported
	Celebrex			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17672025	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413067		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Elbow Deformity; Headache; Liver Function Test Increased	Simponi			S	Subcutaneous			Janssen
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17672031	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200413062			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthropathy; Contraindicated Product Administered; Joint Swelling; Treatment Failure	Simponi Arava Enbrel Methotrexate Orencia Plaquenil /00072603/	S S S S S S	Subcutaneous Subcutaneous	Janssen Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17672253	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411530		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis; Treatment Failure	Simponi Simponi Cosentyx Enbrel Hydroxychloroquine Hydroxychloroquine Rituximab Rituximab Sulfasalazine Methotrexate Celebrex Chloroquine Diphosphate Humira Orencia Xeljanz Erythromycin Morphine			S S S S S S S S S S S S S S S C C	Subcutaneous Unknown Unknown Unknown Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Subcutaneous Unknown Oral Unknown Topical			Janssen Janssen Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17672254	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411531			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Psoriatic Arthropathy	Simponi			S	Subcutaneous			Janssen
	Stelara			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17679287	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009833			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cardiac Disorder; Diarrhoea; Drug Ineffective; Dyspepsia; Headache; Hypercholesterolaemia; Impaired Work Ability; Pain; Therapy Non-Responder	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

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	Sulfasalazine	S	Unknown	Unk		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	716.25 Mg, Unk		Not Reported
	Aspirin /00002701/	C	Unknown	Unk		Not Reported
	Clopidogrel Bisulfate	C	Oral	Unk		Not Reported
	Ezetrol	C	Oral	Unk		Not Reported
	Niaspan Er	C	Unknown	Unk		Not Reported
	Nitroglycerin	C	Transdermal	Unk		Not Reported
	Rosuvastatin Calcium	C	Oral	Unk		Not Reported
	Tylenol /00020001/	C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17687090	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202003003347			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Failure; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17702991	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226210		53 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Propofol Infusion Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Propofol 2% Inyectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedation		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709439	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226654		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			C				Not Reported	
	Azitromicina (7019a)			C	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709444	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-202004003560			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Left Ventricular Hypertrophy	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Tofacitinib			C		Unk		Not Reported	
	Methotrexate [Methotrexate Sodium]			C		Unk		Not Reported	
	Enbrel			C		Unk		Not Reported	
	Infliximab			C		Unk		Not Reported	
	Orencia			C		Unk		Not Reported	
	Rituxan			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709445	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004003658			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Off Label Use; Pneumonitis; Product Availability Issue	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	200 Mg	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	400 Mg, Qd	Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709446	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA- 202004003877			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Tocilizumab			C		200 Mg		Not Reported
	Cholecalciferol			C		3300iu/Mi		Not Reported
	Nitazoxanide			C		500 Mg		Not Reported
	Azithromycin			C		500 Mg		Not Reported
	Bisacodyl			C		5 Mg		Not Reported
	Ceftriaxone			C		1 G		Not Reported
	Enoxaparin Sodium			C		40mg/0.4ml		Not Reported
	Metamizole Sodium			C		1 G		Not Reported
	Midazolam			C		5 Mg		Not Reported
	Etomidate			C		20 Mg		Not Reported
	Esomeprazol			C		40 Mg		Not Reported
	Ondantor			C		8 Mg		Not Reported
	Furosemide			C		20 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709452	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245108		48 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia; Overdose	Pantoprazol			S	Intravenous (not	Unk		Sun

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		otherwise specified)			
Tacrolimus Monohydrate	S	Oral	Unk		Not Reported
Plaquenil	S	Oral	Unk		Not Reported
Pentasa	S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245124		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported
	Ceftriaxone Base			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto 10 Mg, Comprime			C	Oral	Unk		Not Reported
	Pellicule							
	Diffu K			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709619	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR- 1226843		59 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt	Venlafaxine			S	Oral	225 Mg		Teva
Prolonged; Potentiating Drug Interaction	Loxapine Base			S	Oral	155 Mg		Not Reported
	Plaquenil 200 Mg, Comprime			S	Oral	600 Mg		Not Reported
	Pelliculé (Hydroxychloroquine Phosphate)							
	Theralene			S	Oral	50 Mg		Not Reported
	Paracetamol			C	Oral	1 Gram		Not Reported

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Nicopatch 7 Mg/24 H, Dispositif Transdermique De 17,5 Mg/10 Cm ²	C	Transdermal	7 Mg	Not Reported
Diazepam	C	Oral	10 Mg	Not Reported
Atorvastatine	C	Oral	40 Mg	Not Reported
Nicotine	C	Oral	12 Mg	Not Reported
Macrogol 4000	C	Oral		Not Reported
Nebivolol	C	Oral	7.5 Mg	Not Reported
Zopiclone	C	Oral	7.5 Mg	Not Reported
Ramipril	C	Oral	1.25 Mg	Not Reported
Akineton	C	Oral	4 Mg	Not Reported
Ezetimibe	C	Oral	10 Mg	Not Reported
Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet-Dose	C	Oral	75 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709667	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226969		80 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute; Thrombocytopenia	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709805	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-032321			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Maternal	Orencia			S	Intravenous (not			Bristol Myers Squibb

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Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra	S	otherwise specified)						
	Arava	S	Unknown						Not Reported
	Arava	S	Oral	Unk					Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk					Not Reported
	Cimzia	S	Unknown						Not Reported
	Enbrel	S	Subcutaneous						Not Reported
	Folic Acid	S	Subcutaneous						Not Reported
	Fosamax	S	Unknown						Not Reported
	Humira	S	Unknown						Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous						Not Reported
	Methotrexate	S	Unknown						Not Reported
	Phthalylsulfathiazole	S	Unknown						Not Reported
	Prednisone	S	Unknown						Not Reported
	Remicade	S	Intravenous (not otherwise specified)						Not Reported
	Rituxan	S	Intravenous (not otherwise specified)						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709830	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002639			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Treatment Noncompliance	Hydroxychloroquine			S		Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709947	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226986		63 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis;	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported

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Hyperbilirubinaemia	Azitromicina (7019a)	S							Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral		400 Milligram Daily;				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S							Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)		600 Milligram Daily;				Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec	S	Intravenous (not otherwise specified)		3 Dosage Forms Daily; Every 8 Hours				Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710025	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226989		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710046	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226987		36 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 120 Tablets		Not Reported	

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		Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid		S					Not Reported
		Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		S	Oral	400 Milligram Daily; 30 Tablets			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710093	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-GSH201812-004113			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Transplacental	Unk		Concordia	
	Prednisone			S	Transplacental	Unk		Not Reported	
	Azathioprine			S	Transplacental	Unk		Not Reported	
	Tacrolimus			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710318	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588918		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; No Adverse Event; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710626	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226932		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; Drug Ineffective; Drug Intolerance; Rash; Synovitis	Leflunomide			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Parenteral			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710627	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226939		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthritis; Drug Ineffective; Intestinal Perforation	Leflunomide	S	Unknown	Barr
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710635	EXPEDITED (15-DAY)	HO		CA-TEVA-2020-CA-1226954		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Rash; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Cefazolin			S	Intramuscular			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C				Not Reported
	Naproxen			C	Unknown	1000 Milligram Daily;		Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710680	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226998		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Rash; Rheumatoid Arthritis; Unevaluable Event; Urticaria	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Unknown			Barr	
	Cefazolin			S	Unknown			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Amlodipine			C	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Benadryl			C	Unknown			Not Reported	
	Naproxen			C	Unknown			Not Reported	
	Tofacitinib Citrate			C	Unknown			Not Reported	
	Viread			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710682	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1226993		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort;	Leflunomide	S	Oral	Barr
Arthrodesis; Drug	Methotrexate	S	Subcutaneous	Barr
Hypersensitivity; Drug	Cefazolin	S	Unknown	Not Reported
Ineffective; Hand	Certolizumab Pegol	S	Subcutaneous	Not Reported
Deformity; Hospitalisation;	Certolizumab Pegol	S	Subcutaneous	Not Reported
Infection; Rash;	Enbrel	S	Unknown	Not Reported
Rheumatoid Arthritis;	Humira	S	Subcutaneous	Not Reported
Urticaria	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Amlodipine	C		Not Reported
	Arava	C		Not Reported
	Benadryl	C	Unknown	Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Tofacitinib Citrate	C		Not Reported
	Viread	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710749	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-MYLANLABS-2020M1040162			Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Growth Restriction; No Adverse Event; Oligohydramnios; Premature Baby	Omeprazole			S		Unk		Not Reported	
	Calcium Carbonate			S	Transplacental	Unk		Not Reported	
	Metoprolol			S	Transplacental	Unk		Not Reported	
	Dexamethasone			S	Transplacental	Unk		Mylan	
	Dexamethasone			S	Transplacental	Unk		Mylan	
	Albumin			S	Transplacental	Unk		Mylan	
	Penicillin-G			S	Transplacental	Unk		Mylan	

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Prednisone	S	Transplacental	Unk	Mylan
Prednisone	S	Transplacental	Unk	Mylan
Vitamin D /00318501/	S	Transplacental	Unk	Mylan
Hydroxychloroquine	S		Unk	Mylan
Vitamin B Complex /00003501/	S	Unknown	Unk	Mylan
Paracetamol	S	Transplacental	Unk	Mylan
Aminomethylbenzoic Acid	S	Transplacental	Unk	Mylan
Flebogamma Dif /00025201/	S	Transplacental	Unk	Mylan
Magnesium Lactate	S	Transplacental	Unk	Mylan
Bisoprolol Fumarate	S	Transplacental	Unk	Mylan
Privigen	S	Transplacental	Unk	Mylan
Privigen	S	Transplacental	Unk	Mylan
Fluconazole	S	Transplacental	Unk	Mylan
Hydrocortisone	S	Transplacental	Unk	Mylan
Vulmizolin	S	Transplacental	Unk	Mylan
Cefotaxime	S	Transplacental	Unk	Mylan
Cefotaxime	S	Transplacental	Unk	Mylan
Potassium Chloride	S	Transplacental	Unk	Mylan
Folic Acid	S	Transplacental	Unk	Mylan
Bisulepin	S	Transplacental	Unk	Mylan
Etamsylate	S	Transplacental	Unk	Mylan
Nadroparine	S	Transplacental	Unk	Mylan
Ornidazole	S	Transplacental	Unk	Mylan
Methylprednisolone	S	Transplacental	Unk	Mylan
Methylprednisolone	S	Transplacental	Unk	Mylan
Cefixime	S	Transplacental	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710751	NON-EXPEDITED			US-PFIZER INC-2020165061		68 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Methotrexate Sodium			S		Unk		Pfizer
	Arava			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711227	NON-EXPEDITED			US-PFIZER INC-2020167983		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Hypersensitivity; Dyspnoea; Nausea; Swelling; Vomiting; Wheezing	Gabapentin			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Voltaren [Diclofenac Sodium]			S		Unk		Not Reported
	Escitalopram Oxalate			S		Unk		Not Reported
	Linzess			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711246	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227339		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226940		69 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Swelling; Macule; Skin Cancer	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711308	EXPEDITED (15-DAY)		DS	CA-TEVA-2020-CA-1226958		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Mood Swings; Musculoskeletal Stiffness; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr	
	Indometacin			S	Unknown			Not Reported	
	Prednisone			S	Oral	25 Milligram Daily;		Actavis	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Xeljanz	C	Oral	10 Milligram Daily;	Not Reported
Cymbalta	C	Oral	30 Milligram Daily;	Not Reported
Folic Acid	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711319	EXPEDITED (15-DAY)	HO		CA-TEVA-2020-CA-1226935		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	12 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	15 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	12.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Unknown	10 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	17.5 Mg, 1 Every 1 Week		Barr
	Methotrexate			S	Subcutaneous	10 Mg, 1 Every 1 Week		Barr
	Alendronic Acid			S	Unknown	70 Mg, 1 Every 1 Week		Actavis
	Codeine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	200 Milligram Daily;		Not Reported

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Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ciclosporin	C	Unknown 150 Milligram Daily;	Not Reported
Prednisone	C	Unknown 10 Milligram Daily;	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711477	EXPEDITED (15-DAY)		OT	NVSC2020FR109492		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Febrile Neutrophilic Dermatitis; Drug Eruption; Pyrexia	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis
	Prednisone			C	Unknown	15 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711543	EXPEDITED (15-DAY)		DE, OT	ES-ASTELLAS-2020US014740		21 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Amphotericin B, Liposome			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Astellas
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Linezolid			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711604	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226653		72 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mixed Liver Injury	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 200		Teva

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Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	Mg/12h 2 Gram Daily; 2gr/24h	Not Reported
Ceftriaxona (501a)	S			Not Reported
Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S	Oral	4 Dosage Forms Daily; 2 Comp/12h	Not Reported
Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711810	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020167297		78 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree; Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711951	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1226990		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Infection; Leukopenia; Neutropenia	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712080	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226652		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg/24h		Teva	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Single Dose		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712085	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1226657		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Mg		Actavis	
	Plaquenil 200 Mg, Comprimé Pelliculé (Hydroxychloroquine Phosphate)			S	Oral	600 Mg		Not Reported	
	Effexor L.P. 75 Mg, Gélule À Libération Prolongée			S	Oral	150 Mg		Not Reported	
	Acebutolol (Chlorhydrate D')			C	Oral	400 Mg		Not Reported	
	Oxazepam			C	Oral	100 Mg		Not Reported	
	Enoxaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))			C	Subcutaneous	4000 Iu		Not Reported	
	Macrogol 4000			C	Oral	2 Df		Not Reported	
	Amlodipine			C	Oral	10 Mg		Not Reported	

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	Chlorhydrate De Clomipramine	C	Oral	150 Mg	Not Reported
	Zopiclone	C	Oral	7.5 Mg	Not Reported
	Chlorhydrate De Nicardipine	C	Oral	60 Mg	Not Reported
	Hydrochlorothiazide	C	Oral	25 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712129	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226773		49 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712237	EXPEDITED (15-DAY)		HO	GR-PFIZER INC-2011075813		56 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pyrexia; Urinary Tract Infection; Urinary Tract Pain	Medrol			S	Oral	4 Mg, 1x/Day		Pfizer
	Neoral-Sandimmune (Ciclosporin)			S	Oral	50 Mg, 2x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Mg, 1x/Day		Not Reported
	Thyrohormone			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712238	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587205			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nephrotic Syndrome	Mycophenolate Mofetil			S	Unknown			Not Reported

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Azathioprine Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712368	EXPEDITED (15-DAY)		OT	NVSC2020CA111106		78 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use In Unapproved Indication; Retinal Toxicity	Hydroxychloroquine			S	Unknown	5.3 Mg/Kg, Qd		Novartis
	Hydroxychloroquine			S	Unknown	2.7 Mg/Kg, Qd		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712393	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226967		65 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712394	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226772		30 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

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Ceftriaxona (501a)			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712720	EXPEDITED (15-DAY)		HO, OT	SE-PFIZER INC-2020167060		16 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Prednisolone			S	Oral	10-15 Df		Pfizer	
	Sertraline Hcl			S	Oral	750 Mg		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10-15 Df		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17713099	DIRECT	Y	LT, OT			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17713314	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428290		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17714374	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200428608			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Subcutaneous			Not Reported	
	Anakinra			S				Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17714446	EXPEDITED (15-DAY)		OT	NVSC2020CA111134		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retinal Toxicity	Hydroxychloroquine			S	Unknown	7.1 Mg/Kg, Qd		Novartis	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715382	EXPEDITED (15-DAY)		HO	NVSC2020FR109498		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Febrile Neutrophilic Dermatitis; Product Use In Unapproved Indication; Pyrexia; Rash Pustular; Skin Plaque	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715446	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-033914			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Bid		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Zopiclone			C	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715582	EXPEDITED (15-DAY)		OT	CA-ASSERTIO THERAPEUTICS, INC.- CA-2020DEP000202		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac Potassium			S	Unknown	50 Mg, Unk		Assertio Therapeutics	
Alopecia; Arthralgia; Blood	Actemra			S	Unknown	Unk		Not Reported	
Cholesterol Increased;	Apo Prednison			S	Unknown	Unk		Not Reported	
Contraindicated Product	Arava			S	Unknown	Unk		Not Reported	
Administered; Drug	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
Ineffective; General	Cimzia			S	Subcutaneous	400 Mg, Unk		Not Reported	
Physical Health	Cimzia			S	Unknown	Unk		Not Reported	
Deterioration; Headache;	Cortisone Acetate			S	Unknown	Unk		Not Reported	
Hypersensitivity;	Desoximetasone			S	Oral	Unk		Not Reported	
Hypertension; Joint	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported	
Swelling; Maternal	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported	
Exposure During	Fosamax			S	Unknown	Unk		Not Reported	
Pregnancy;	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
Musculoskeletal Stiffness;	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
Pain; Pemphigus;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
Pericarditis; Product Use	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported	
Issue; Rheumatic Fever;	Methotrexate			S	Subcutaneous	25 Mg, Weekly		Not Reported	
Rheumatoid Arthritis;	Methotrexate			S	Oral	25 Mg, Unk		Not Reported	
Swelling; Swollen Joint	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Count Increased;	Orencia			S	Unknown	Unk		Not Reported	
Synovitis; Systemic Lupus	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported	
Erythematosis;	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported	
Therapeutic Product Effect	Prednisone			S	Unknown	Unk		Not Reported	
Decreased; Treatment	Pseudoephedrine Hcl			S	Unknown	Unk		Not Reported	
Failure; Type 2 Diabetes									
Mellitus									

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	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S	Unknown	Unk		Not Reported
	Salazopyrine	S	Unknown	Unk		Not Reported
	Simponi	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Oral	Unk		Not Reported
	Sulfathalidine	S	Unknown	Unk		Not Reported
	Xeljanz	S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715715	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020561		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
	Rocephin			S	Oral	2 Gram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715746	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-020590			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715772	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020598			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Antinuclear Antibody Positive; Arthralgia;	Meloxicam			S	Unknown	Unk		Aurobindo	
	Arava			S	Unknown	Unk		Not Reported	

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Arthritis; Blister; Dry Mouth; Headache; Hypersensitivity Vasculitis; Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling; Lymphadenopathy; Menorrhagia; Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement; Peripheral Swelling; Rheumatoid Arthritis; Sjogren'S Syndrome; Systemic Lupus Erythematosus; Vasculitis	Belimumab Breo Ellipta Celebrex Colchicine Dexilant Estrojel Methotrexate Methotrexate Plaquenil Prednisone Rituximab Sulfasalazine Ventolin Hfa	S S S S S S S S S S S S S	Unknown Unknown Unknown Oral Topical Oral Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk 60 Milligram, Once A Day Unk, Once A Day Unk Unk 200 Milligram, Two Times A Day 50 Milligram Unk Unk Unk Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715790	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226775		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715834	EXPEDITED (15-DAY)		HO	SE-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245240		16 YR	Female	SWE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Fatigue;	Sertraline			S	Oral	750 Milligram, Unk		Sun
Intentional Overdose;	Prednisolone			S	Oral	10-15st.		Not Reported
Intentional Self-Injury;	Plaquenil			S	Oral	10-15 St.		Not Reported
Somnolence; Tachycardia								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	12367074	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-034237		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
Increased; Alopecia;	Orencia			S	Unknown	760 Milligram, Qwk		Bristol Myers Squibb
Arthralgia; Aspartate	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb
Aminotransferase					otherwise specified)			
Increased; Basal Cell	Alendronate Sodium			S	Oral	70 Milligram, Qwk		Not Reported
Carcinoma; Blood	Codeine Sulphate			S	Unknown	Unk		Not Reported
Parathyroid Hormone	Enbrel			S	Unknown	25 Milligram, 2 Times/Wk		Not Reported
Decreased; C-Reactive	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
Protein Increased;	Enbrel			S	Unknown	25 Milligram, Qwk		Not Reported
Condition Aggravated;	Enbrel			S	Unknown	25 Milligram, Q2wk		Not Reported
Drug Eruption; Drug	Enbrel			S	Unknown	50 Milligram		Not Reported
Hypersensitivity; Drug	Enbrel			S	Unknown	25.0 Milligram, Qwk		Not Reported
Ineffective; Drug	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
Intolerance; Drug	Hydroxychloroquine			S	Oral	20 Milligram, Qd		Not Reported
Tolerance; Drug Tolerance	Hydroxychloroquine			S	Oral	200 Milligram, Qd		Not Reported
Decreased; Erythema;	Leflunomide			S	Oral	20 Milligram		Not Reported
Gastric Disorder;	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
Granuloma Skin;	Methotrexate Sodium			S	Subcutaneous	15 Milligram, Qwk		Not Reported
Hypercalcaemia;	Methotrexate Sodium			S	Subcutaneous	17.5 Milligram, Qwk		Not Reported
Hypersensitivity;	Methotrexate Sodium			S	Subcutaneous	10 Milligram, Qwk		Not Reported
Inflammation; Infusion								
Related Reaction; Loss Of								
Personal Independence In								
Daily Activities;								
Musculoskeletal Stiffness;								
Pain; Panniculitis;								
Peripheral Swelling;								
Product Use Issue; Rash;								

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Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Ulcer	Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Unknown	360 Milligram, Qmo	Not Reported
	Simponi	S	Unknown	680 Milligram, Qmo	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Q4wk	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	70 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Q4wk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Bid	Not Reported
	Rituximab	S	Unknown	1000 Milligram, Qd	Not Reported

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Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Actemra	S	Intravenous (not otherwise specified)	360 Milligram, Qmo	Not Reported
Actemra	S	Intravenous (not otherwise specified)	680 Milligram, Q4wk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	2.68 Milligram, Q4wk	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qmo	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Q2wk	Not Reported
Myochrysine	S	Intramuscular	25 Milligram, Qwk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Oral	500 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Qmo	Not Reported
Tocilizumab	S	Unknown	680 Milligram, Q4wk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Alendronic Acid	S	Unknown	70 Milligram, Qwk	Not Reported
Etanercept	S	Unknown	25.0 Milligram, Qwk	Not Reported
Etanercept	S	Unknown	50 Milligram, Qwk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Naproxen	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous	40 Milligram, Qcycle	Not Reported
Celebrex	S	Unknown		Not Reported
Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
Prednisone	C	Unknown	20 Milligram	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

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Ciclosporin	C	Unknown	150 Milligram 1 Every 24 Days	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Qd	Not Reported
Prednisolone	C	Unknown	10 Milligram, Qd	Not Reported
Humira	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	12913793	EXPEDITED (15-DAY)		DS, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091772		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb
Abdominal Pain Upper;					otherwise specified)			
Adverse Drug Reaction;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
Alopecia; Anti-Cyclic	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
Citrullinated Peptide	Actemra			S	Subcutaneous	Unk		Not Reported
Antibody Positive;	Actemra			S	Intravenous (not	Unk		Not Reported
Arthralgia; Arthropathy;					otherwise specified)			
Blister; Condition	Actemra			S	Unknown	Unk		Not Reported
Aggravated; Discomfort;	Arava			S	Oral	20 Milligram		Not Reported
Drug Ineffective; Drug	Arava			S	Oral	Unk		Not Reported
Intolerance; Duodenal	Arava			S	Unknown	Unk		Not Reported
Ulcer Perforation; Fatigue;	Cetirizine Hydrochloride			S	Unknown	10 Milligram, Qd		Not Reported
General Physical Health	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
Deterioration;	Cimzia			S	Subcutaneous	Unk		Not Reported
Glossodynia; Hand	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
Deformity; Helicobacter	Cortisone Acetate			S	Oral	25 Milligram		Not Reported
Infection; Hepatic Enzyme	Desoximetasone			S	Cutaneous	Unk		Not Reported
Increased; Hip	Desoximetasone			S	Oral	Unk		Not Reported
Arthroplasty;	Desoximetasone			S	Oral	Unk		Not Reported
Hypersensitivity; Infusion								
Related Reaction; Injury;								
Intentional Product Use								
Issue; Joint Swelling;								
Knee Arthroplasty; Live								
Birth; Maternal Exposure								
During Pregnancy;								
Musculoskeletal Stiffness;								
Pain; Pemphigus;								

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Pericarditis; Rash;	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Rheumatoid Arthritis;	Enbrel	S	Unknown	Unk	Not Reported
Rheumatoid Factor	Enbrel	S	Subcutaneous	Unk	Not Reported
Positive; Swelling;	Folic Acid	S	Unknown	1 Milligram	Not Reported
Synovitis; Systemic Lupus	Folic Acid	S	Unknown	5 Milligram	Not Reported
Erythematosis;	Folic Acid	S	Unknown	500 Milligram	Not Reported
Therapeutic Product Effect	Fosamax	S	Oral	Unk	Not Reported
Decreased; Treatment	Fosamax	S	Unknown	Unk	Not Reported
Failure; Wound	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Sunconjunctival	Unk	Not Reported
	Humira	S	Sunconjunctival	40 Milligram	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	1 Gram, Bid	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, Qd	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not	Unk	Not Reported

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		otherwise specified)		
Rituxan	S	Intravesical	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1 Dosage Form	Not Reported
Xeljanz	S	Unknown	5 Milligram, Q12h	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Zyrtec [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	25 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	1 Milligram	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	5 Milligram	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	25 Milligram	Not Reported

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Kevzara	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Prednisone	S	Unknown	5 Unk	Not Reported
Prednisone	S	Unknown	1 Milligram	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported

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Cetirizine	S	Oral	10 Milligram	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Apo-Folic Acid	S	Unknown	5 Milligram	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Milligram	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Diclofenac	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	25 Milligram	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	Unk Unk, Bid	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Oral	25 Milligram	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cortisone	S	Unknown	25 Milligram	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Winpred	S	Oral	Unk	Not Reported

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Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported
Leflunomide	C	Oral		Not Reported
Prednisolone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	13969809	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP018054		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
Anti-Cyclic Citrullinated	Hydroxychloroquine			S	Unknown	Unk		Apotex
Peptide Antibody Positive;	Hydroxychloroquine			S	Oral	Unk		Apotex
Arthralgia; Arthropathy; C-	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
Reactive Protein	Leflunomide			S	Unknown	Unk		Apotex
Abnormal; C-Reactive	Apo-Leflunomide			S	Endocervical	Unk		Apotex
Protein Increased;	Actemra			S	Unknown	Unk		Not Reported
Condition Aggravated;	Actemra			S	Intravenous (not	8 Mg/Kg, Unk		Not Reported
Diarrhoea; Disease					otherwise specified)			
Recurrence; Drug	Arava			S	Unknown	Unk		Not Reported
Hypersensitivity; Drug	Cimzia			S	Subcutaneous	Unk		Not Reported
Ineffective; Hepatic	Enbrel			S	Unknown	Unk		Not Reported
Enzyme Increased;								
Hypertension; Joint								
Swelling; Loss Of								
Personal Independence In								
Daily Activities; Lower								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Respiratory Tract Infection; Nausea; Off Label Use; Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Pulmonary Mass; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg, Qd	Not Reported
	Methotrexate	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Imuran /00001501/	C	Unknown		Not Reported
	Gold	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown	50 Mg, Bid	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Atorvastatin Calcium	C	Unknown	Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported

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Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Furosemid /00032602/	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C			Not Reported
Lyrica	C	Unknown	75 Mg, Qd	Not Reported
Naproxen	C	Unknown	500 Mg, Qd	Not Reported
Nifedipine	C	Unknown	Unk	Not Reported
Palafer	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	10 Mg, Bid	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Toloxin /00017701/	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	50 Mg, Qd	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Xarelto	C	Unknown	Unk	Not Reported
Zinc Citrate	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Unk	Not Reported
Hydroxychloroquine	C	Unknown	200 Mg, Q.O.Wk.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	14502886	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-007063		53 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability;	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qmo		Not Reported	
	Actemra			S	Intravenous (not	8 Milligram/Kilogram, Qd		Not Reported	

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Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non-Responder	Arava	S	Oral	200 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qmo	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram, Qd	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	200 Milligram, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Remicade	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Tofacitinib Citrate	S	Oral	5 Milligram, 2every1day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Apo-Hydroxyquine	S	Oral	400 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2 Gram, Q6mo	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Actonel	C	Unknown		Not Reported
	Sulfasalazine	C	Oral	Unk	Not Reported
	Sulfasalazine	C	Oral	500 Milligram, Bid	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	15935909	EXPEDITED (15-DAY)		DE, OT	IT-ACCORD-104696		67 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion; Drug Interaction; Haemoptysis; International Normalised Ratio Decreased; Labelled Drug-Drug Interaction Medication Error; Platelet Count Decreased; Product Administration Error; Pyrexia	Hydrochlorothiazide			S		Unk		Not Reported	
	Lorazepam			S		Unk, Also Received As Concomitant.		Accord	
	Montelukast			S		Unk, Also Received As Concomitant.		Not Reported	
	Acetylsalicylic Acid			S		Unk, Also Received As Concomitant		Not Reported	
	Celecoxib			S		Unk, Also Received As Concomitant.		Not Reported	
	Hydroxychloroquine			S		Unk, Also Received As Concomitant.		Not Reported	
	Influenza Vaccine			S		Unk		Not Reported	
	Warfarin			S		Regimen 1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	16081389	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013165		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness;	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo	
	Risedronate Tablet			S	Oral	35 Milligram, Every Week		Aurobindo	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	300 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported	

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Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Once A Day	Not Reported
	Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram, Once A Day	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil	S	Oral	300 Milligram, Once A Day	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	35 Milligram, Every Week	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1 Gram, Cyclical (1 Every 1 Day)	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk,Once A Day	Not Reported
	Actonel	S	Unknown	35 Milligram, Every Week	Not Reported
	Hydroxychloroquine	S	Unknown	Unk,Once A Day	Not Reported
	Hydroxychloroquine	S	Unknown	20 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	300 Milligram	Not Reported
	Anakinra	S	Subcutaneous	100.0 Milligram	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	C	Oral	5.0 Milligram, Two Times A Day	Not Reported
	Risedronate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	16358401	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-049379		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort;	Orencia	S	Unknown	Unk	Bristol Myers Squibb
Abdominal Pain Upper;	Arava	S	Unknown	Unk	Not Reported
Arthralgia; Cardiac Failure;	Biaxin	S	Unknown	Unk	Not Reported
Cardiac Failure	Celebrex	S	Unknown	Unk	Not Reported
Congestive; Cough;	Ciprofloxacin	S	Unknown	Unk	Not Reported
Diarrhoea; Drug	Clindamycin	S	Unknown	Unk	Not Reported
Hypersensitivity; Drug	Codeine	S	Unknown	Unk	Not Reported
Ineffective; Drug	Enalapril	S	Unknown	Unk	Not Reported
Intolerance; Dyspnoea;	Enbrel	S	Unknown	Unk	Not Reported
Gastric Disorder;	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Headache; Hepatic	Fosamax	S	Unknown	Unk	Not Reported
Steatosis; Hypertension;	Hctz	S	Unknown	Unk	Not Reported
Loss Of Employment;	Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
Malaise; Nausea; Product	Keflex [Cefalexin]	S	Unknown	Unk	Not Reported
Use Issue; Rash;	Levaquin	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Losartan	S	Unknown	Unk	Not Reported
Decreased	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Metoprolol Tartrate	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
	Pariet	S	Unknown	Unk	Not Reported
	Penicillin G 2-Amino-4-Methoxy-6-Methylpyrim.	S	Unknown	Unk	Not Reported
	Plaquenil S	S	Unknown	Unk	Not Reported
	Cephalexin Monohydrate	S	Unknown	Unk	Not Reported
	Gliclazide	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Isoniazid	S	Unknown	Unk	Not Reported

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Lopressor	S	Unknown		Not Reported
Losartan Potassium	S	Unknown		Not Reported
Tecta	S	Unknown		Not Reported
Xeljanz	S	Oral	50 Milligram, Bid	Not Reported
Enalapril Maleate	S	Unknown		Not Reported
Penicillin G [Benzylpenicillin Sodium]	S	Unknown	Unk	Not Reported
Cephalexin [Cefalexin]	S	Unknown	Unk	Not Reported
Clindamycin Phosphate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	10 Milligram	Not Reported
Venofer	C	Unknown		Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Iron Sucrose	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	8.5 Milligram, Qd	Not Reported
Atenolol	C	Unknown		Not Reported
Colchicine	C	Unknown		Not Reported
Coversyl [Perindopril Erbumine]	C	Unknown		Not Reported
Leucovorin [Folinic Acid]	C	Unknown		Not Reported
Levothyroxine Sodium	C	Unknown		Not Reported
Ranitidine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	16782017	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA- 2019VAL000468			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Bloody Discharge; Drug	Demerol	S	Unknown	Unk	Validus
Hypersensitivity; Drug	Meperidine Hydrochloride	S	Unknown	Unk	Validus
Intolerance; Fatigue;	Pethidine Hydrochloride	S	Unknown	Unk	Validus
Infection; International	Leflunomide	S	Unknown	Unk	Not Reported
Normalised Ratio	Plaquenil /00072603/	S	Oral	400 Mg, Qd	Not Reported
Fluctuation; Lyme	Erythromycin	S	Unknown	Unk	Not Reported
Disease; Nausea;	Arava	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Bisoprolol Fumarate	S	Unknown	Tablet	Not Reported
Incomplete; Vomiting	Methotrexate	S	Oral	1 Df, Qw	Not Reported
	Metronidazole	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	Unk	Not Reported
	Cefaclor	S	Unknown	Unk	Not Reported
	Erythromycin	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Pregabalin	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Erythromycin Estolate	S	Unknown	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Arthrotec	S	Unknown	Unk	Not Reported
	Plaquenil /00072603/	S	Unknown	Unk	Not Reported
	Norfloxacin	S	Unknown	400 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Unk	Not Reported
	Celecoxib	S	Oral	200 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	S	Unknown	Unk	Not Reported
	Bisoprolol	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
	Diclofenac Sodium And	S	Unknown	Unk	Not Reported
	Misoprostol				

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Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	16879886	EXPEDITED (15-DAY)		OT	GR-ACCORD-156263		59 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Exemestane			S	Unknown	Unk		Not Reported
	Ramipril			S	Unknown	Unk		Accord
	Levothyroxine			S	Oral	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Dicoumarol			S	Unknown	Unk		Not Reported
	Levothyroxine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17299448	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527600		61 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celecoxib			C	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone

C

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17351623	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA- 2020VAL000067			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
Erythromycin			S	Unknown	Unk		Not Reported	
Erythromycin Estolate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levofloxacin	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Plaquenil /00072603/	S	Oral	400 Mg, Qd	Not Reported
Plaquenil /00072603/	S	Oral	Unk	Not Reported
Arthrotec	S	Unknown	Unk	Not Reported
Levofloxacin Hemihydrate	S	Unknown	Unk	Not Reported
Diclofenac Sodium And Misoprostol	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17426809	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551542			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17475675	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20190801306			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Alopecia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Sepsis; Therapeutic Response Decreased; White Blood Cell Count Decreased	Simponi			S	Subcutaneous	365 Days		Janssen	
	Simponi			S				Janssen	
	Arava			S	Oral			Not Reported	
	Arava			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Sertraline Hydrochloride			S	Unknown			Not Reported	
	Plaquenil /00072602/			C				Not Reported	
	Amitriptyline			C				Not Reported	
	Constella			C				Not Reported	
	Reactine /00884302/			C	Oral			Not Reported	
	Aerius /01009701/			C				Not Reported	
	Zopiclone			C		7.5 Mg 1/2 -1 Tablet		Not Reported	
	Zomig			C				Not Reported	
	Vitamin C /00008001/			C				Not Reported	
	Acyclovir /00587301/			C	Unknown			Not Reported	
	Levofloxacin			C	Unknown			Not Reported	
	Lyrica			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17557583	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318935		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Off Label Use;	Simponi			S	Subcutaneous			Janssen	
	Enbrel			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Arthritis;	Orencia	S	Unknown	Not Reported
Sleep Disorder; Treatment	Sulfasalazine	S	Unknown	Not Reported
Noncompliance	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17600443	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2020SA076630		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Hydroxychloroquine Sulfate			S	Oral	5 Mg/Kg, Qd		Sanofi
Antibody Test Positive;	Hydroxychloroquine Sulfate			S	Oral	5 Mg Qd		Sanofi
Arthritis; Arthropathy;	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
Body Height Below	Naproxen			S	Oral	5 Mg, Qd		Not Reported
Normal; Bone Density	Naproxen			S	Oral	3 Mg Qd		Not Reported
Decreased; C-Reactive	Naproxen			S	Unknown			Not Reported
Protein Increased;	Naproxen			S				Not Reported
Condition Aggravated;	Prednisone			S	Oral	5 Mg, Bid		Not Reported
Diarrhoea; Dizziness;	Prednisone			S	Oral	3 Mg, Bid		Not Reported
Drug Ineffective; Drug	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
Intolerance; Drug Specific	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
Antibody Present;	Prednisone			S	Oral	3 Mg, Bid		Not Reported
Gastroenteritis Viral;	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
Human Anti-Human	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
Antibody Test;	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
Hypocalcaemia;	Prednisone			S	Oral	1.3 Mg Bid		Not Reported
Hypokalaemia;	Prednisone			S	Unknown	Unk		Not Reported
Hypotension;	Prednisone			S	Oral	50 Mg, Bid		Not Reported
Immunodeficiency;	Prednisone			S	Unknown	50 Mg		Not Reported
Impaired Quality Of Life;	Prednisone			S	Oral			Not Reported
Joint Destruction; Joint	Prednisone			S	Unknown			Not Reported
Effusion; Joint Injury;	Immunoglobulins			S	Intravenous (not			Not Reported
Juvenile Idiopathic	[Immunoglobulins Nos]				otherwise specified)			
Arthritis; Liver Function								
Test Abnormal; Loss Of								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthrits; Prescribed Underdose; Product Use Issue; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2, Qow	Not Reported
	Methotrexate	S			Not Reported
	Methotrexate	S			Not Reported
	Triamcinolone Acetonide	S	Intra-articular		Sanofi
	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Triamcinolone Acetonide	S	Unknown		Sanofi
	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg, Bid	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Unknown	50 Mg	Not Reported
	Anakinra	S	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
Anakinra	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Qow	Not Reported
Humira	S	Unknown		Not Reported
Humira	S			Not Reported
Humira	S	Subcutaneous	Form: Solution	Not Reported
Humira	S			Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk Unk, Q6w	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Infliximab	S	Unknown	5 Mg	Not Reported
Infliximab	S	Unknown	3 Mg/Kg, Q6w	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S		250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Q2m	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Mg	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S					Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow			Not Reported
Triamcinolone Hexacetonide	S	Other				Not Reported
Triamcinolone Hexacetonide	S	Unknown	Unk			Not Reported
Folic Acid	C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17605318	EXPEDITED (15-DAY)		OT	AU-SA-2020SA072232		34 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous;	Enoxaparin Sodium			S		200 Mg		Sanofi
Adrenal Haemorrhage;	Acetylsalicylic Acid			S		100 Mg		Not Reported
Atrial Septal Defect;	Hydroxychloroquine			S		200 Mg		Sanofi
Cerebral Infarction; Deep Vein Thrombosis;	Cyclophosphamide Monohydrate			C	Intravenous (not otherwise specified)	1.5 G		Not Reported
Myocardial Hypoperfusion;	Heparin Sodium			C				Not Reported
Myocarditis; Pulmonary Embolism; Pulmonary Infarction; Thrombotic Microangiopathy; Transient Ischaemic Attack	Rituximab			C		1 G		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17611349	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20151008546			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Contraindicated Product Administered;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

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Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Arava	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Cortisone	C	Unknown	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17664343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009853			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Condition Aggravated; Contraindicated Product Administered; Drug Intolerance; Headache; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17678663	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224966		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	Unit Dose : 200 Mg 400mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17691116	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1225788		62 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hepatitis; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S S	Oral	400 Milligram Daily;		Not Reported Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17693985	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419445			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17694005	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200419292		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Simponi			S	Subcutaneous			Janssen	
	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S				Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Xeljanz			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715963	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020588			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715964	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020558		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Bisoprolol			S	Unknown	1.25 Milligram, Once A Day		Aurobindo	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716067	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010203			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Hepatotoxicity	Leflunomide			S	Unknown	Unk		Apotex	
	Prednisone			S	Unknown	6 Mg, Qd		Not Reported	
	Pregabalin			S	Unknown	150 Mg, Qd		Not Reported	
	Trazodone			S	Unknown	25 Mg, Qd		Apotex	
	Imuran /00001501/			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589484			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Bupropion			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716273	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0122393			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Intolerance; Haematochezia; Hepatic Enzyme Increased; Joint Swelling; Muscle Spasms; Nausea; Neuropathy Peripheral; Rash; Skin Burning Sensation	Atorvastatin			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Acetaminophen			C	Oral			Not Reported

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Asa Ec	C	Oral	Not Reported
Folic Acid	C	Oral	Not Reported
Vitamin D3	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716326	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227005		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716375	EXPEDITED (15-DAY)		HO	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-049454			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Herpes Simplex Hepatitis	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Zydus Pharm
	Prednisone			S	Unknown	5 Milligram, Qd		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Metronidazole			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716389	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229781		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Azathioprine			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Ivax	
	Methotrexate			S	Unknown			Barr	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716579	EXPEDITED (15-DAY)		HO	MX-ADVANSZ PHARMA-202004004174			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716653	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588584			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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	Orencia		S	Intravenous (not otherwise specified)				Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown				Not Reported	
	Celebrex		C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716681	EXPEDITED (15-DAY)		HO, OT	RO-ACCORD-136273		56 YR	Female	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Nodule	Methotrexate			S				Accord	
	Sulfasalazine			S				Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Insulin			C		40 Ui		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716778	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1225767		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Unresponsive To Stimuli; Ventricular Fibrillation	Azithromycin			S	Oral	On Day 1		Not Reported	
	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	
	Hydroxychloroquine			S	Oral	800 Milligram Daily; On Day 1		Teva	
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716808	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.-2020ES03040			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Per Day		Cipla	

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	Dolquine	S	Oral	400 Milligram, Per Day	Not Reported
	Kaletra	S	Oral	2 Dosage Form, Bid (Every 12 Hours; 2u/12 H)	Not Reported
	Kaletra	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716812	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589371			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Feeding Disorder; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-033895			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported

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Pregnancy; Pain;	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Pemphigus; Rash;	Cimzia	S	Subcutaneous	Unk	Not Reported
Rheumatoid Arthritis;	Desoximetasone	S	Oral	Unk	Not Reported
Swelling; Systemic Lupus	Etanercept	S	Subcutaneous	Unk	Not Reported
Erythematosis; Wound	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milliliter, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717114	NON-EXPEDITED			US-PFIZER INC-2020168411			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Enbrel			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported

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Humira	S	Unk	Not Reported
Orencia	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717266	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2588343		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Arthropathy; C- Reactive Protein Decreased; Crohn'S Disease; Death; Drug Ineffective; Drug Intolerance; Feeling Jittery; Joint Swelling; Limb Discomfort; Localised Infection; Malaise; Musculoskeletal Disorder; Nausea; Neck Pain; Night Sweats; Pain; Peripheral Swelling; Purulent Discharge; Pustular Psoriasis; Synovitis; Tachycardia; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 128.0 Days		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 176.0 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration:4 Months		Not Reported
	Xeljanz			S	Oral	Therapy Duration:6 Months		Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Calcium			C	Oral			Not Reported
	Celebrex			C	Unknown			Not Reported
	Elavil [Amitriptyline Hydrochloride]			C	Unknown			Not Reported

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	Ergocalciferol	C	Oral	Not Reported
	Leucovorin Calcium	C	Oral	Not Reported
	Lorazepam	C	Oral	Not Reported
	Magnesium	C	Unknown	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Valtrex	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717380	EXPEDITED (15-DAY)	DE		NVSC2020FI113463		7 YR	Female	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia; Product Use In Unapproved Indication; Respiratory Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Etanercept			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717567	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2020-IN- 001291			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ototoxicity; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Prednisolone			C	Unknown	40 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	5 Milligram, Qd		Not Reported
	Prednisolone			C	Unknown	10 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588809		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive	Actemra			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Protein Abnormal; Drug	Enbrel	S	Subcutaneous	Not Reported
Ineffective; Joint Swelling;	Hydroxychloroquine	S	Unknown	Not Reported
Red Blood Cell	Methotrexate	S	Unknown	Not Reported
Sedimentation Rate	Sulfasalazine	S	Unknown	Not Reported
Abnormal	Folic Acid	C		Not Reported
	Naproxen	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718400	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1227002			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug	Leflunomide			S	Oral	20 Milligram Daily;		Barr
Ineffective; Epistaxis;	Methotrexate			S	Subcutaneous			Barr
Headache; Insomnia; Joint	Azathioprine			S	Oral	200 Milligram Daily;		Not Reported
Swelling; Nausea; Rash;	Azathioprine			S	Oral	50 Milligram Daily;		Not Reported
Transaminases Increased;	Azathioprine			S	Oral	150 Milligram Daily;		Not Reported
Vasculitis	Mycophenolate Mofetil			S	Oral	2 Gram Daily;		Teva
	Mycophenolate Mofetil			S	Oral	1000 Milligram Daily;		Teva
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Imuran			S	Oral	50 Milligram Daily;		Not Reported
	Imuran			S	Oral	150 Milligram Daily;		Not Reported
	Imuran			S	Oral	200 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Ketoprofen			C				Not Reported
	Prednisone			C				Not Reported
	Prolia Pre-Filled Syringe.			C	Subcutaneous			Not Reported
	Preservative-Free							

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quetiapine	C	Oral	25 Milligram Daily;	Not Reported
Rituximab	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588638			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718533	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588767		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported

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Orencia	S	Intravenous (not otherwise specified)	Not Reported
Naprosyn [Naproxen]	C		Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718649	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-20K-144-3380621-00		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Pancreatitis Acute	Kaletra 200/50			S	Oral			Not Reported	
	Metilprednisolona			S	Intravenous (not otherwise specified)			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Dolquine			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588479			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Vomiting	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Meloxicam	C		Not Reported
	Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718922	EXPEDITED (15-DAY)		DS	CA-ROCHE-2588501		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Gait Disturbance; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Rituxan			S	Intravenous drip	579.0		Not Reported
	Enbrel			S	Subcutaneous	9 Months		Not Reported
	Humira			S	Subcutaneous	7 Months		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Xeljanz			S	Intravenous (not otherwise specified)	2 Years		Not Reported
	Xeljanz			S	Unknown	2 Years		Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17719461	EXPEDITED (15-DAY)		OT	NVSC2020SE113735		59 YR	Female	SWE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Neurosensory; Dizziness; Ear Discomfort; Nausea; Tinnitus	Methotrexate			S	Unknown	"Nov 2016 Højdes Mtx Till 8 Tab/V".		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown	6 Tabletter	Novartis
	Methotrexate	S	Unknown	7 Tabletter	Novartis
	Methotrexate	S	Unknown	"6 Tab. Methotrexat/V +5 Mg Prednisolon Under Mång År".	Novartis
	Plaquenil	S	Unknown		Not Reported
	Prednisolone	C	Unknown	5 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720803	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3378772-00		49 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Lopinavir/Ritonavir			S	Oral			Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720916	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020972		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram (1 Total)		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720923	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020973		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Milligram, Once A Day	Aurobindo
	Azithromycin	S			Aurobindo
	Metamizol	S	Intravenous (not otherwise specified)	2 Gram, Four Times/Day	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Once A Day	Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram 1 Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720925	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020974		47 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo	
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported	
	Tocilizumab			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17721027	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245414		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun	
	Hidroxicloraquina (2143a)			S	Oral	200 Mg/24h		Not Reported	

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Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600mg/24h	Not Reported
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2gr/24h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17722744	DIRECT	Y	DE			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Test Positive; Emergency Care	Hydroxychloroquine			S	Oral			Actavis
	Kaletra			S	Oral			Abbvie

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	12489538	EXPEDITED (15-DAY)		OT	CA-009507513-1606CAN007831		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Remeron			S	Oral	15 Mg		Merck
	Enbrel			S	Unknown	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Dosage Form Not Specified		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Dosage Form Not Specified		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	12913683	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-		43 YR	Female	CAN

FDA Adverse Event Reporting System

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Detailed Report

BMS-2016-092891

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	25 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Oral	10 Milligram		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cortisone			S	Oral	Unk, Prn		Not Reported
	Cortisone Acetate			S	Topical	25 Milligram		Not Reported
	Cortisone Acetate			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Oral	5 Milligram		Not Reported
	Folic Acid			S	Oral	1 Milligram		Not Reported

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Folic Acid	S	Unknown	1 Dosage Form	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	1 Milligram	Not Reported
Folic Acid	S	Unknown	500 Milligram	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Oral	Unk	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	5 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Hydrochloride;Pseudoephedrine				
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Apo Folic	S	Unknown	5 Milligram	Not Reported
Apo Prednison	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
Methotrexate	S	Unknown	Unk, Qd	Not Reported
Methotrexate	S	Oral	Unk, Qd	Not Reported
Methotrexate	S	Oral	20 Milligram, Qd	Not Reported

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Methotrexate	S	Oral	25 Milligram, Qwk	Not Reported
Methotrexate	S	Intra-arterial	25 Milligram, Qwk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	10 Milligram	Not Reported
Cortisone	S	Topical	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	13165249	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886155		67 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Atorvastatin Calcium			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Digoxin			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Furosemide			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Nifedipine			C				Not Reported
	Palafer			C				Not Reported
	Pantoprazole			C				Not Reported
	Prednisone			C				Not Reported
	Synthroid			C				Not Reported
	Toloxin [Digoxin]			C				Not Reported
	Valsartan			C				Not Reported
	Vitamin D3			C	Unknown			Not Reported

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Xarelto	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Zinc Citrate	C		Not Reported
Naproxen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	13250722	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894453		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown	Cyclical		Not Reported
	Arava			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 4 Years Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years Cyclical		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	14471157	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-004461		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Treatment Failure; Viral Upper Respiratory Tract Infection	Orencia			S	Unknown			Bristol Myers Squibb	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Actemra			S	Unknown	160 Mg, Unk		Not Reported	
	Meloxicam			S	Unknown			Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	20 Milligram, Qwk		Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Mobicox			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulphate			C	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			C	Unknown	Unk		Not Reported	
	Depo-Medrol			C	Intra-articular	80 Milligram, Qd		Not Reported	
	Diclofenac			C	Unknown	Unk		Not Reported	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	
	Pantoprazole Magnesium			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	15096452	EXPEDITED (15-DAY)		CA, DE, DS, OT	PHHY2018DE028935			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Septal Defect; Congenital Cardiovascular	Ezetimibe			S	Transplacental	Unk		Novartis	

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Anomaly; Death; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Product Monitoring Error; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril	S	Transplacental	20 Mg, Unk (Maternal Dose)	Not Reported
	Simvastatin	S	Transplacental	Unk	Not Reported
	Metamizole	S	Transplacental	Unk	Not Reported
	Salbutamol	S	Transplacental	Unk	Not Reported
	Tacrolimus	S	Transplacental	Unk	Not Reported
	Rivaroxaban	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	400 Mg, Qd	Not Reported
	Prednisolone	S	Transplacental	Unk	Not Reported
	Pantoprazole	S	Transplacental		Not Reported
	Aliskiren	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	S	Transplacental	100 Mg, Qd	Not Reported
	Torem	S	Transplacental	100 Mg, Qd	Not Reported
	Rasilez	S	Transplacental	300mg/D Unk	Not Reported
	Rasilez	S	Transplacental	100 Mg/D Unk	Not Reported
	Enoxaparin	S	Transplacental	Unk	Not Reported
	Nicotine	S	Transplacental	Unk	Not Reported
	Mifegyne	C	Unknown	Unk	Not Reported
	Cytotec	C	Unknown	Unk	Not Reported
	Cyclophosphamide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	15100606	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0751		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported

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Orencia	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Prednisone	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tocilizumab	S		Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Methotrexate	C	Oral	Not Reported
Methotrexate	C	Unknown	Not Reported
Prednisone	C		Not Reported
Desoximetasone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	15102944	EXPEDITED (15-DAY)		OT	PHHY2018DE028933		24 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Exposure During Pregnancy; Maternal Exposure During Pregnancy; Premature Delivery; Product Monitoring Error	Ezetimibe			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Novartis	
	Aliskiren			S	Unknown	Unk, Unknown Freq. (0-5 Gw)		Not Reported	
	Ramipril			S	Unknown	20 Mg, Unk		Not Reported	
	Torsemide			S	Unknown	0-14 Gw		Not Reported	
	Simvastatin			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported	
	Metamizole			S	Unknown	Unk		Not Reported	
	Salbutamol			S	Unknown	Unk, Unknown Freq. (0-14 Gw)		Not Reported	
	Tacrolimus			S	Unknown			Not Reported	

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Rivaroxaban	S	Unknown	0-14 Gw	Not Reported
Rivaroxaban	S	Unknown	Unk, Unknown Freq. (0-5 Gw)	Not Reported
Hydroxychloroquine	S	Unknown	0-14 Gw	Not Reported
Prednisolone	S	Unknown	0-14 Gw	Not Reported
Acetylsalicylic Acid	S	Unknown	0-14 Gw	Not Reported
Pantoprazole	S	Unknown	0-14 Gw	Not Reported
Nicotine	S	Unknown		Not Reported
Enoxaparin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	15416072	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187971		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			C	Unknown			Not Reported
	Desoximetasone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	15593099	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018445495		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Aphthous Ulcer; Blood Cholesterol Increased; Constipation; Diarrhoea; Headache; Oral Candidiasis; Sinusitis	Xeljanz Xr			S		11 Mg, Unk		Pfizer	
	Xeljanz Xr			S		11 Mg, Unk		Pfizer	
	Xeljanz Xr			S		11 Mg, 1x/Day		Pfizer	
	Xeljanz Xr			S		11 Mg, Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S		200 Mg, 2x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported	
	Cymbalta			C		Unk		Not Reported	
	Clonazepam			C		Unk		Not Reported	
	Hydroxychloroquine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	15964988	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-ACCORD-107431			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ramipril			S	Transplacental	20 Mg Per Day, Exposure Duration: 0-13+6 Weeks		Accord	
	Simvastatin			S	Transplacental	From Gestational Week 0-14		Accord	
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Accord	
	Ezetimibe			S	Transplacental	Also Received As Suspect, From Gestational Week 0-14		Not Reported	
	Pantoprazole			S	Transplacental	40 Mg/D, 0-13.6 Gestational Week		Not Reported	
	Salbutamol			S	Transplacental	From Gestational Week 0-		Not Reported	

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			14	
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin	S	Transplacental	Unk	Not Reported
Hydroxychloroquine	S	Transplacental	From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental	300 Mg/D, 0-4.6 Gestational Week	Not Reported
Prednisolone	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid Sandoz	S	Transplacental		Not Reported
Rivaroxaban	S	Transplacental		Not Reported
Torsemide	S	Transplacental	From Gestational Week 0-14	Not Reported
Novaminsulfon	S	Transplacental	Unk, Trimester: First, Probably Only In Hospital In Week 5	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Clexane	S	Transplacental	200 Mg/D (2x100)	Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Cytotec	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Mifegyne	C	Transplacental	Unk, 13.6 Gestational Week	Not Reported
Cyclophosphamide/Cyclophosphamide Monohydrate	C	Transplacental	3000 Mg Cumulative, Preconceptional	Not Reported
Enoxaparin	C	Transplacental	Unk Unk, Unknown Freq. (0-14 Gw), Also Received As Concomitant.	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	16080946	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-013597		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Hypersensitivity; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Rosuvastatin Tablet			S	Unknown	Unk		Aurobindo
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Milligram, Two Times A Day		Not Reported
	Methotrexate			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	16478155	EXPEDITED (15-DAY)		CA, DE, HO, OT	FR-ACCORD-135124			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Bowing Of Long Bones; Congenital Osteodystrophy; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Low Birth Weight Baby; Patent	Esomeprazole/Esomeprazole			S	Transplacental			Not Reported
	Magnesium/Esomeprazole Sodium Plaquenil			S	Transplacental	Strength: 200 Mg, 1 Dosage Form, Once Daily (Qd)		Not Reported

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Ductus Arteriosus; Premature Baby; Premature Separation Of Placenta; Right-To-Left Cardiac Shunt	Diffu K	S	Transplacental	1 Dosage Form, Once Daily (Qd)	Not Reported
	Cortancyl	S	Transplacental	Strength: 5 Mg, 1 Dosage Form, Once Daily (Qd)	Not Reported
	Imurel	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	16710864	EXPEDITED (15-DAY)		DS, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA- 2019VAL000394			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Demerol			S	Unknown	Unk		Validus
	Plaquenil /00072603/			S	Oral	400 Mg, Qd		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported
	Lyrica			S	Unknown	Unk		Not Reported
	Meperidine /00016301/			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	16719064	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217711		68 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blastomycosis; Contraindicated Product Administered; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Knee Arthroplasty; Neoplasm Malignant; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive	Arava			S	Oral	Unk Unk, Unk		Sanofi	
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported	
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi	
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported	
	Orencia			S	Unknown	750 Mg, Qw		Not Reported	
	Celebrex			C	Unknown	Unk Unk, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	16880699	EXPEDITED (15-DAY)		OT	CA-ROCHE-2415168			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Meloxicam			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tylenol			S	Unknown			Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17182156	EXPEDITED (15-DAY)		OT	NVSC2019CA073777			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Liver Injury; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Psoriatic Arthropathy; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Diclofenac Sodium			S	Unknown	Unk		Novartis
	Cosentyx			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
Humira			S	Subcutaneous	Solution		Not Reported	
Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	

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Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk (Injection)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Quetiapine	C	Unknown	Unk	Not Reported
Ramipril	C	Unknown	Unk	Not Reported
Calcium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17259008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516331		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Drug Ineffective; Joint	Actemra			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Tramadol Hydrochloride	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17339418	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530858		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous 100 Mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Triamcinolone	S	Unknown	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Injectable Suspension Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17401839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542463		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17560345	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309909		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Stelara			S	Subcutaneous			Janssen
Adverse Drug Reaction;	Simponi			S	Subcutaneous			Janssen
Alopecia; Anti-Cyclic	Remicade			S	Intravenous (not	Powder For Solution		Janssen
Citrullinated Peptide					otherwise specified)	Intravenous		
Antibody Positive;	Remicade			S	Subcutaneous			Janssen
Arthralgia; Discomfort;	Remicade			S	Intravenous (not			Janssen
Drug Ineffective; Drug					otherwise specified)			
Intolerance; Fatigue;	Remicade			S	Unknown			Johnson And Johnson
Glossodynia; Hand	Cetirizine			S	Unknown			Johnson And Johnson
Deformity; Hepatic	Hydrochloride/Pseudoephedrine							
Enzyme Increased; Hip	Hydrochloride							
Arthroplasty;	Cimzia			S	Subcutaneous	Single-Use Prefilled		Not Reported
Hypersensitivity; Infusion						Syringe		
Related Reaction; Joint	Cortisone Acetate			S	Unknown			Not Reported
Swelling; Knee	Cortisone Acetate			S	Topical			Not Reported
Arthroplasty; Maternal	Desoximetasone			S	Oral	And Oral		Not Reported
Exposure During	Enbrel			S	Subcutaneous			Not Reported
Pregnancy;	Folic Acid			S	Unknown	Unknown For 5.0 Mg,		Not Reported
Musculoskeletal Stiffness;						Through Oral 25.0 Mg,		
Off Label Use; Pain;	Folic Acid			S	Subcutaneous			Not Reported
Pemphigus; Pericarditis;	Fosamax			S	Oral			Not Reported
Product Use Issue; Rash;	Humira			S	Subcutaneous	Unknown For 5.0 Mg,		Not Reported
Rheumatoid Arthritis;						Through Oral 25.0 Mg,		
Rheumatoid Factor	Leflunomide			S	Unknown			Not Reported
Positive; Synovitis;								
Systemic Lupus								
Erythematosis;								
Therapeutic Product Effect								
Decreased; Treatment								
Failure; Wound								

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Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Topicort /00370301/	S	Subcutaneous	Not Reported
Topicort /00370301/	S	Topical	Not Reported
Xeljanz	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C		Not Reported

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29-Apr-2020	17583318	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202003001754			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis Infective; Bartonella Test Positive; Cat Scratch Disease; Device Dislocation; Erythema; Inflammation; Pneumonia; Purulence; Pyrexia; Tenderness	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17661978	EXPEDITED (15-DAY)		DS, OT	BR-ADVANZ PHARMA-202003002616			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Bedridden; Blindness; Cardiac Disorder; Corneal Disorder; Drug Dependence; Gait Inability; General Physical Health Deterioration; Renal Disorder	Hydroxychloroquine			S	Unknown	Unk, Qod		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17669289	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010048		32 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Oral	20 Mg, Qd		Apotex	
	Certolizumab Pegol			S	Subcutaneous	400 Mg, (Cyclical)		Not Reported	
	Certolizumab Pegol			S	Subcutaneous	400 Mg, Q.O.Wk.		Not Reported	

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	Certolizumab Pegol	S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Certolizumab Pegol	S	Subcutaneous	200 Mg, Q.Wk.		Not Reported
	Certolizumab Pegol	S	Subcutaneous	400 Mg, Unk		Not Reported
	Enbrel	S	Unknown	Unk, Q.Wk.		Not Reported
	Methotrexate	S	Subcutaneous	Unk		Not Reported
	Sulfasalazine	S	Unknown	Unk		Not Reported
	Prednisone	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17678101	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202004002848			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Drug Ineffective; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17682573	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANSZ PHARMA-202003002315			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Condition Aggravated; Death; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S	Oral	800 Mg, Qd, Film Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Paracetamol			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Macrogol 3350			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Sufentanil			C		Unk		Not Reported
	Propofol			C		Unk		Not Reported
	Voriconazole			C		Unk		Not Reported

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	Norepinephrine	C	Unk	Not Reported
	Cisatracurium	C	Unk	Not Reported
	Midazolam	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17705879	EXPEDITED (15-DAY)		HO	CH-ABBVIE-20K-151-3376752-00		70 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral	800/200 Mg		Not Reported	
	Kaletra			S	Oral	400/100 Mg		Not Reported	
	Plaquenil			S	Oral	Initial Dose		Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Actemra			C	Intravenous drip			Not Reported	
	Co-Amoxi			C				Not Reported	
	Triatec			C				Not Reported	
	Metfin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17716184	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3380425-00		58 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Piperacillina Sodica/Tazobactam Sodico			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229703			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Iron Abnormal; Rheumatoid Arthritis	Ciclosporin	S	Unknown	Ivax
	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721359	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588833		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Conjunctivitis; Drug Ineffective; Fatigue; Joint Swelling; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Amlodipine Besilate			C	Unknown			Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydrochlorothiazide	C	Oral	Not Reported
	Lyrica	C	Oral	Not Reported
	Mavik	C	Oral	Not Reported
	Olopatadine Hydrochloride	C	Ophthalmic	Not Reported
	Prednisone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721370	EXPEDITED (15-DAY)		OT	ES-ADVANSZ PHARMA-GSH201807-002384			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Pulmonary Oedema; Congestive Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721385	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589389		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eye Disorder; Fatigue	Actemra			S	Unknown			Not Reported	
	Apo-Acetaminophen			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Dilaudid			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588807		33 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Erosion;	Actemra			S	Unknown			Not Reported	

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C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Arava	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721388	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-GSH201907-001665			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Depressed Level Of Consciousness;	Hydroxychloroquine			S	Unknown	Unk		Concordia
Diarrhoea; Fatigue;	Methotrexate			S	Unknown	Unk		Not Reported
Headache; Lethargy;	Methotrexate			S				Not Reported
Malaise; Mental Status Changes; Muscular Weakness; Myalgia; Nausea; Pyrexia; Tachycardia; Unresponsive To Stimuli; West Nile Viral Infection	Prednisone			S	Unknown	6 Mg, Qd (Part Of A Regimen That Involved Tapering Of The Dose)		Not Reported
	Methylprednisolone			S	Unknown	High Dose		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Glucocorticoids			S	Unknown			Not Reported
	Sulfamethoxazole-Trimethoprim			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589542			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Swelling; Nausea; Pain;	Actemra			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapeutic Product Effect Decreased	Arava	S	Unknown	Not Reported
	Bacitracin	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Neomycin Sulfate	S	Unknown	Not Reported
	Polymyxin B Sulfate	S	Unknown	Not Reported
	Prednisone	C	Intramuscular	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589692			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721425	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA- GSH201801-000313			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Hydroxychloroquine			S	Oral	4 Dosage Form, Tablet		Concordia

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Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Sinus Tachycardia; Torsade De Pointes; Toxicity To Various Agents; Ventricular Arrhythmia; Ventricular Extrasystoles; Ventricular Tachycardia	Ondansetron Hydrochloride	S	Intravenous (not otherwise specified)	4 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721434	EXPEDITED (15-DAY)		HO, OT	IT-ADVANS PHARMA-GSH201804-001135			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Back Pain; Blood Lactate Dehydrogenase Increased; C-Reactive Protein Increased; Movement Disorder; Mycobacterial Infection; Mycobacterium Avium Complex Infection; Osteomyelitis; Osteomyelitis; Osteomyelitis Bacterial; Pyrexia	Hydroxychloroquine			S	Oral	Unk		Concordia
	Prednisone			S	Oral	50 Mg, Qd, Administered Initially Which Was Later Tapered To 5 Mg/Day		Not Reported
	Prednisone			S	Oral	5 Mg		Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721454	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245365		63 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Paracetamol			S	Oral	1 Gr Cada 8 Horas		Ohm Lab
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721456	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245370		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721521	EXPEDITED (15-DAY)		OT	ES-HETERO- HET2020ES00451		81 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Condition Aggravated	Levofloxacin			S	Oral	500 Mg, Qd		Hetero	
	Dolquine			S	Oral	200 Mg, Qd		Not Reported	
	Metronidazol /00012501/			S	Oral	Unk		Not Reported	
	Amoxicilina + Acido Clavulonico			S	Oral	Unk, Tid (1 Comp/8h)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721556	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589838		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Tenderness; Adverse Drug Reaction;	Actemra			S	Unknown			Not Reported	
Arthralgia; Arthropathy;	Apo-Leflunomide			S	Unknown			Not Reported	
Drug Ineffective; Fatigue;	Enbrel			S	Unknown			Not Reported	
Groin Pain; Joint Injury; Joint Range Of Motion	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Joint Swelling;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Methotrexate	S	Unknown	Not Reported
Pain; Pain In Extremity;	Rabeprazole Sodium	C	Unknown	Not Reported
Peripheral Swelling;	Tramadol Hydrochloride	C	Oral	Not Reported
Retinal Toxicity;	Xeljanz	C	Unknown	Not Reported
Rheumatoid Arthritis;				
Sleep Disorder; Swelling				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721569	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100957			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Enbrel			S		25 Mg		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	40 Mg, Solution Subcutaneous		Not Reported
	Actemra			S				Not Reported
	Bupropion			C				Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721604	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589413		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721617	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588791		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Sleep Disorder; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Celebrex			C	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721663	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588955			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Folic Acid			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589500			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588902		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ketorolac	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721734	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227334		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg, 1 Ertapenem (2881a)			S	Intravenous (not otherwise specified)	C/24 H		Not Reported	
				S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721767	EXPEDITED (15-DAY)		HO, LT, OT	NL-ADVANSZ PHARMA-MAPI_00011545			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Hydroxychloroquine			S	Oral	Unk, Coated Tablet		Concordia	
	Methotrexate			S	Oral	20 Mg, Weekly		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721783	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588811		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported	
	Naproxen			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Surgery; Synovitis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721865	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA- 202004004073			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia	Hydroxychloroquine			S	Unknown	Unk Coated Tablet		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721870	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590364			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722005	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034287			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Condition	Orencia	S	Unknown	Unk	Bristol Myers Squibb
Aggravated; Drug	Enbrel	S	Unknown	Unk	Not Reported
Intolerance; Headache;	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Qd	Not Reported
Nausea; Rheumatoid	Infliximab	S	Unknown	Unk	Not Reported
Arthritis; Treatment	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
Failure; Vomiting	Morphine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722162	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3377866-00		78 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qt Prolonged	Kaletra			S	Oral			Not Reported
	Midazolam			S	Unknown			Not Reported
	Midazolam			S				Not Reported
	Dolquine			S	Oral	A Compressed Breakfast And Dinner		Not Reported
	Propofol			S	Unknown			Not Reported
	Propofol			S				Not Reported
	Omnice Ocas			C				Not Reported
	Manidol Hta			C				Not Reported
	Rilast Turbuhaler			C				Not Reported
	Simvastatina			C				Not Reported
	Kalpress			C				Not Reported
	Cortic			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722246	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032531			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Tocilizumab	S	Subcutaneous		Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Etanercept	S	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590161			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosis	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Unknown			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Phthalylsulfathiazole			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	

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Sulfasalazine			S	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722271	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-02		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Mobicox			S	Unknown			Boehringer Ingelheim	
	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tylenol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722333	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1227342		81 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Condition Aggravated	Levofloxacin (2791a)			S	Oral	500 Milligram Daily;		Teva	
	Amoxicilina Acido Clavulanico Sala			S	Oral	1 Comp/8h		Teva	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	1 Comp/24h, 200 Mg		Not Reported	
	Metronidazol (1966a)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722337	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES- 1227335		50 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722485	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229997		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Oral	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Risedronate Sodium			S	Unknown	35 Mg, 1 Every 1 Week		Teva
	Methotrexate			S	Subcutaneous	175 Mg		Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Risedronate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722622	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228475			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	otherwise specified) Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722635	EXPEDITED (15-DAY)		DS, HO, OT	NVSC2020CA110668		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Adalimumab			S	Subcutaneous	Unk		Novartis
Alanine Aminotransferase	Codeine Phosphate			S	Unknown	Unk		Not Reported
Abnormal; Alanine	Cosentyx			S	Unknown	Unk		Not Reported
Aminotransferase	Ciclosporin Sandoz			S	Oral	Unk		Not Reported
Increased; Arthralgia;	Cyclosporine			S	Oral	Unk		Not Reported
Arthritis; Arthropathy;	Leflunomide			S	Oral	Unk		Not Reported
Aspartate	Methotrexate			S	Subcutaneous	15 Mg, Other (Solution For Injection)		Not Reported
Aminotransferase	Methotrexate			S	Subcutaneous	17.5 Mg, Other (Solution For Injection)		Not Reported
Increased; Basal Cell	Methotrexate			S	Subcutaneous	10 Mg, Other (Solution For Injection)		Not Reported
Carcinoma; Blood	Methotrexate			S	Oral	4 Df, Qw		Not Reported
Creatinine Increased;	Methotrexate			S	Subcutaneous	12.5 Mg, Qw (Solution For Injection)		Not Reported
Blood Parathyroid	Abatacept			S	Unknown	Unk		Not Reported
Hormone Decreased;	Alendronate Sodium			S	Unknown	70 Mg, Other		Not Reported
Blood Pressure Systolic	Apo Ibuprofen			S	Oral	600 Mg, Other		Not Reported
Increased; C-Reactive	Apo-Cyclosporine			S	Unknown	Unk (Oral Solution)		Not Reported
Protein Abnormal;	Apo-Cyclosporine			S	Oral	Unk (Oral Solution)		Not Reported
Contraindicated Product	Apo-Leflunomide			S	Oral	Unk		Not Reported
Administered; Decreased	Apo-Leflunomide			S	Unknown	Unk		Not Reported
Appetite; Diarrhoea; Drug								
Eruption; Drug								
Hypersensitivity; Drug								
Intolerance; Entesopathy;								
Erythema; Fatigue; Fear								
Of Injection; General								
Physical Health								
Deterioration; Granuloma								
Skin; Headache;								
Hypercalcaemia;								
Inflammation; Infusion								
Related Reaction;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Insomnia; Joint Injury;	Apremilast	S	Unknown	Unk	Not Reported
Joint Swelling;	Apremilast	S	Unknown	60 Mg, Bid	Not Reported
Musculoskeletal Stiffness;	Apremilast	S	Oral	30 Mg, Bid	Not Reported
Nausea; Off Label Use;	Arava	S	Oral	20 Mg, Qd	Not Reported
Pain; Panniculitis;	Celebrex	S	Oral	200 Mg, Bid	Not Reported
Peripheral Swelling;	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Product Use Issue;	Cimzia	S	Subcutaneous	Unk	Not Reported
Psoriatic Arthropathy;	Enbrel	S	Unknown	25 Mg, Other	Not Reported
Rash; Rash Pruritic; Red	Enbrel	S	Subcutaneous	Unk	Not Reported
Blood Cell Sedimentation	Enbrel	S	Unknown	25 Mg, Biw	Not Reported
Rate; Red Blood Cell	Etanercept	S	Unknown	Unk	Not Reported
Sedimentation Rate	Etanercept	S	Unknown	Unk	Not Reported
Increased; Rheumatoid	Etanercept	S	Subcutaneous	Unk	Not Reported
Arthritis; Rheumatoid	Etanercept	S	Subcutaneous	Unk	Not Reported
Nodule; Skin Necrosis;	Golimumab	S	Subcutaneous	Unk	Not Reported
Skin Ulcer; Synovitis;	Humira	S	Subcutaneous	Unk	Not Reported
Tendonitis; Tenosynovitis;	Hydroxychloroquine	S	Unknown	Unk	Not Reported
Therapy Non-Responder;	Ibuprofen	S	Oral	600 Mg, 6qd	Not Reported
Tongue Disorder;	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
Treatment Failure; Ulcer;	Ibuprofen	S	Oral	600 Mg, Other	Not Reported
Urticaria	Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Other	Not Reported
	Motrin	S	Unknown	6 Df, Qd	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Motrin	S	Oral	600 Mg, Qd	Not Reported
	Motrin	S	Oral	600 Mg, Other	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Otezla	S	Oral	30 Mg, Bid	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Otezla	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Oral	600 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	500 Mg, Other	Not Reported
Sulfasalazine	S	Unknown	Unk (Tablet)	Not Reported
Tocilizumab	S	Unknown	360 Mg, Other	Not Reported
Ustekinumab	S	Subcutaneous	Unk	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Actonel	C	Oral	35 Mg, Qw	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Methotrexate Sodium	C	Oral	Unk Unk, Qw	Not Reported
Mogadon	C	Unknown	5 Mg, Other	Not Reported
Naproxen	C	Unknown	500 Mg, Other	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Nitrazepam	C	Unknown	5 Mg, Other	Not Reported
Oxycodone	C	Unknown	10 Mg, Other	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oxycodone	C	Unknown	40 Mg, Other	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Mg, Other	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Mg, Other	Not Reported
Oxyneo	C	Unknown	40 Mg, Other	Not Reported
Oxyneo	C	Unknown	10 Mg, Other	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Uloric	C	Unknown	80 Mg, Bid	Not Reported
Uloric	C	Oral	80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Mg, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Uloric	C	Oral	80 Mg, Bid	Not Reported
Vitamin D3	C	Oral	2000 Iu, Other	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722636	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228692			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	Not Reported
Remicade	S	Subcutaneous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722673	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010329			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage; Joint Stiffness; Joint Swelling; Pruritus; Psoriasis	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Cimzia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	300 Mg, Qd		Not Reported
	Alendronate Sodium			C	Oral	70 Mg, Unk		Not Reported
	Atenolol			C	Unknown	3 Df, Unk		Not Reported
	Certolizumab Pegol			C	Subcutaneous	Unk		Not Reported
	Chlordiazepoxide W/Clidinium Bromide			C	Oral	Unk		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Oral	40 Mg, Unk		Not Reported
	Hydrochlorothiazide			C	Oral	25 Mg, Qd		Not Reported
	Lorazepam			C	Oral	1 Mg, Qd		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Oral	Unk		Not Reported
	Trimebutine			C	Unknown	1 Df, Q.12h		Not Reported

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589505			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Seborrheic Dermatitis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589415			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722899	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228686			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy;	Diclofenac Sodium			S	Unknown			Actavis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Contraindicated Product	Prednisone	S	Oral	Actavis
Administered; Discomfort;	Methotrexate	S	Intra-arterial	Barr
Drug Ineffective; Fatigue;	Methotrexate	S	Unknown	Barr
Glossodynia; Hand	Adalimumab	S	Subcutaneous	Not Reported
Deformity; Maternal	Apo-Prednisone	S	Unknown	Not Reported
Exposure During	Arava	S	Oral	Not Reported
Pregnancy; Off Label Use;	Cetirizine Hydrochloride	S	Unknown	Not Reported
Pain; Pemphigus; Product	Cetirizine Hydrochloride	S	Unknown	Not Reported
Use Issue; Rash;	Cetirizine Hydrochloride	S		Not Reported
Rheumatoid Arthritis;	Cimzia	S	Subcutaneous	Not Reported
Swelling; Systemic Lupus	Cimzia	S	Subcutaneous	Not Reported
Erythematosis; Wound	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S		Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Cetirizine	S	Unknown	Not Reported
Hydrochloride,Pseudoephedrine			
Hydrochloride			
Cetirizine	S	Unknown	Not Reported
Hydrochloride,Pseudoephedrine			
Hydrochloride			
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722905	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034249		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Orencia			S	Unknown	750 Milligram, Qd		Bristol Myers Squibb
	Cimzia			S	Unknown	200 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	5 Milligram		Not Reported
	Leflunomide			S	Oral	10 Milligram		Not Reported
	Methotrexate			S	Unknown	5 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Prednisone			C	Unknown	50 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723476	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590185		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723713	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020165921		48 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil Sulfate			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724074	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020166830		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction;	Zithromax	S	Oral	Unk	Pfizer
Electrocardiogram Qt	Plaquenil [Hydroxychloroquine	S	Oral	Unk	Not Reported
Prolonged; Off Label Use;	Phosphate]				
Product Use In	Cefotaxime Mylan	C		Unk	Not Reported
Unapproved Indication					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724350	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010222		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Swelling; Pulmonary Mass	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, 1 Every 4 Weeks		Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Unk		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	Unk		Not Reported
	Cranberry /01512301/			C	Unknown	Unk		Not Reported
	Olopatadine			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Quinapril Hydrochloride			C	Unknown	Unk		Not Reported
	Sandoz Rabeprazole			C	Unknown	Unk		Not Reported
	Singulair			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586330			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Ill-	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

Defined Disorder; Mental Disorder; Muscle Injury; Myalgia; Pruritus; Rash	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725036	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034298		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Abatacept			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium + Vit D			C	Unknown			Not Reported
	Hydrocortisone			C	Unknown	2 Every One Days		Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown	20 Milligram, Qd		Not Reported
	Tylenol Arthritis Pain			C	Unknown	2 Dosage Form, Bid		Not Reported
	Xarelto			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725448	EXPEDITED (15-DAY)		OT	NVSC2020CA062017		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug	Methotrexate Sodium			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

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Intolerance; Fatigue; Gastrointestinal Disorder; Joint Swelling; Malaise; Musculoskeletal Stiffness; Nausea; Pain; Spinal X- Ray Abnormal; Stress; Swelling; Tender Joint Count; Therapeutic Response Decreased	Sulfasalazine	S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725450	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020166847		45 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, Daily		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Inipomp			C	Unknown	Unk		Not Reported
	Rovamycine [Spiramycin]			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Xarelto			C	Oral	Unk		Not Reported
	Diffu K			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725452	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC- 2020169681		57 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Advagraf			C	Oral	4 Mg, 1x/Day		Not Reported
	Calcimagon D3			C		Unk		Not Reported

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Cefuroxime	C	Intravenous (not otherwise specified)	1.5 G, 3x/Day	Not Reported
Co-Amoxicillin	C	Intravenous (not otherwise specified)	1.2 G, 3x/Day	Not Reported
Flagyl [Metronidazole]	C	Oral	500 Mg, 3x/Day	Not Reported
Folic Acid	C		Unk	Not Reported
Lasix [Furosemide]	C	Intravenous (not otherwise specified)	40 Mg, 1x/Day	Not Reported
Myfortic	C	Oral	720 Mg, 2x/Day	Not Reported
Tazobac	C	Intravenous (not otherwise specified)	2.25 G, 3x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725640	EXPEDITED (15-DAY)		HO, OT	CA-SHIRE-CA202014192			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Intentional Product Use Issue; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use;	Human Normal Immunoglobulin			S	Unknown			Shire	
	Human Normal Immunoglobulin			S	Intravenous (not otherwise specified)	70 Gram		Shire	
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/Week		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	280 Milligram, 1x/2wks		Not Reported	
	Anakinra			S	Subcutaneous	50 Milligram, 1x/Day:Qd		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram, 1x/Week		Not Reported	
	Enbrel			S	Subcutaneous	25 Milligram		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	5 Milligram/Kilogram, 1x/Day:Qd		Not Reported	
	Infliximab			S	Unknown	5 Milligram		Not Reported	

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Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Infliximab	S	Intravenous (not otherwise specified)	3 Milligram, 1x/Week	Not Reported
	Methotrexate	S	Subcutaneous	Unk Unk, 1x/Week	Not Reported
	Naproxen	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Milligram, 1x A Month	Not Reported
	Prednisone	S	Oral	10 Milligram, 1x/Day:Qd	Not Reported
	Prednisone	S	Oral	3 Milligram	Not Reported
	Sulfasalazine	S	Oral	250 Milligram, 1x/Day:Qd	Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone Hexacetonide	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725765	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC- 20200432974		72 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Durogesic Matrix			S	Transdermal	Patch 25 Mcg/H : 1 Tous Les 3 Jours		Janssen
	Plaquenil /00072602/			S	Oral	800 Mg/Jour Du 22 Au 23.03.2020, 400 Mg/Jour Du 24 Au 26.03.2020, 600 Mg/Jour Du 26 Au 30.03.2020		Not Reported
	Doxycycline			S	Oral			Not Reported
	Azithromycine			S	Oral			Not Reported
	Amoxicillin And Clavulanate			S	Intravenous drip			Not Reported
	Potassium Enoxaparin			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725781	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020166844		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Bradycardia; Incorrect Product Administration	Zithromax	S	Oral	250 Mg, 1x/Day	Pfizer
Duration; Off Label Use; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported
	Cefotaxime Mylan	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725844	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034644		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Ineffective	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Oral	5.0 Milligram, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588805		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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Sulfasalazine

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17726004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589054			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17726026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589868		70 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17726302	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020922		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Risedronate			S	Unknown	35 Milligram, Every Week		Aurobindo	
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram Per Kilogram		Not Reported	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	20 Milligram, Every Hour		Not Reported	
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported	
	Arava			S	Oral	20 Milligram, Once A Day		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Every Week		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported	
	Methotrexate			S	Subcutaneous	17.5 Milligram		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			S	Intravenous (not	Unk		Not Reported	

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Rituximab	S	otherwise specified)	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	S	Subcutaneous	5 Milligram, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17726305	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-020924		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock;	Risedronate			S	Unknown	5 Milligram		Aurobindo
Arthralgia; Bedridden;	Actemra			S	Unknown	Unk		Not Reported
Condition Aggravated;	Apo-Leflunomide			S	Oral	20 Milligram, Once A Day		Not Reported
Drug Ineffective;	Arava			S	Unknown	Unk		Not Reported
Fibromyalgia; Foot	Celebrex			S	Unknown	Unk		Not Reported
Fracture; General Physical	Cimzia			S	Subcutaneous	Unk		Not Reported
Health Deterioration;	Enbrel			S	Subcutaneous	Unk		Not Reported
Hepatitis; Loss Of	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
Personal Independence In	Methotrexate			S	Unknown	Unk		Not Reported
Daily Activities; Lower	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
Limb Fracture; Mobility	Orencia			S	Unknown	Unk		Not Reported
Decreased; Myocardial	Plaquenil			S	Unknown	Unk		Not Reported
Infarction; Off Label Use;	Prednisolone			S	Unknown	Unk		Not Reported
Osteoporosis; Rheumatoid	Prednisone			S	Unknown	Unk		Not Reported
Arthritis; Therapeutic	Simponi			S	Subcutaneous	Unk		Not Reported
Product Effect Incomplete;	Sulfasalazine			S	Oral	500 Milligram		Not Reported
Treatment Failure	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram		Not Reported
	Desoximetasone			C	Unknown	5 Milligram, Once A Day		Not Reported

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	Leflunomide	C	Unknown	Unk		Not Reported			
	Prednisone Acetate	C	Unknown	5 Milligram, Once A Day		Not Reported			
	Tylenol	C	Unknown	Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17727439	DIRECT	Y	DE			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction; Cardiac Arrest; Cardiogenic Shock; Renal Failure	Hydroxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral			Not Reported	
	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:500 Mg/Vil;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	12788076	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-077476		41 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Abatacept			S	Subcutaneous	Unk		Bristol Myers Squibb	
Alanine Aminotransferase Abnormal; Alanine Aminotransferase Increased; Arthralgia; Arthropathy; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Creatinine Increased; Blood Parathyroid Hormone Decreased; Blood Pressure Systolic Increased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Decreased Appetite; Diarrhoea; Drug	Abatacept			S	Unknown	Unk		Bristol Myers Squibb	
	Etanercept			S	Subcutaneous			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	25 Milligram,2 Every One Week		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Unknown	25 Milligram		Not Reported	
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Oral	Unk		Not Reported	
	Infliximab			S	Unknown	Unk		Not Reported	



Detailed Report

Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Fatigue; Fear Of Injection; General Physical Health	Infliximab	S	Intravenous (not otherwise specified)	400 Milligram	Not Reported
Deterioration; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Infusion Related Reaction; Insomnia; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain; Panniculitis; Peripheral Swelling; Product Use Issue; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Therapy Non-Responder; Tongue Disorder; Treatment Failure; Ulcer; Urticaria	Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
	Ustekinumab	S	Subcutaneous		Not Reported
	Apremilast	S	Unknown	60 Milligram, Bid	Not Reported
	Apremilast	S	Oral	30 Milligram, Bid	Not Reported
	Ibuprofen	S	Oral	600 Milligram, Q4h	Not Reported
	Golimumab	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	Unk	Not Reported
	Ciclosporin	S	Oral	0.6 Milligram	Not Reported
	Ciclosporin	S	Oral	Unk	Not Reported
	Apo-Cyclosporine	S	Oral		Not Reported
	Apo-Cyclosporine	S	Unknown	Unk	Not Reported
	Apo-Ibuprofen	S	Oral	600 Milligram	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Otezla	S	Oral	30 Milligram, Bid	Not Reported
	Otezla	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Stelara	S	Unknown	Unk	Not Reported
	Motrin [Ibuprofen]	S	Oral	600 Milligram, Qd	Not Reported
	Motrin [Ibuprofen]	S	Oral	6 Dosage Form, Qd	Not Reported
	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Bid	Not Reported

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		otherwise specified)		
Codeine	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	2.5 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Oral	4 Dosage Form, Qwk	Not Reported
Methotrexate Sodium	S	Unknown	10 Milligram, Qwk	Not Reported
Methotrexate Sodium	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	17.5 Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous	12.5 Milligram, 1 Every 1 Week	Not Reported
Arava	S	Oral	20 Milligram, 1 Every 1 Days	Not Reported
Celebrex	S	Oral	2000 Milligram, 2 Every 1 Days	Not Reported
Cosentyx	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	1000 Milligram, 2 Every 1 Day	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram, Bid	Not Reported
Uloric	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	0.6 Milligram	Not Reported
Nitrazepam	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Oral	Unk	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Febuxostat	C	Unknown	80 Milligram, Bid	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unk	Not Reported
Dexilant	C	Unknown	Unk	Not Reported
Gravol	C	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Acide Folique	C	Unknown	Unk	Not Reported
Motrin Children	S	Unknown	Unk	Not Reported
Prednisone	C	Unknown		Not Reported
Methotrexate	C	Oral	Unk, 1 Every 1 Week	Not Reported
Actonel	C	Oral	35 Milligram, Qwk	Not Reported
Cannabis Sativa	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported
Vitamin D 3	C	Oral	2000 International Unit	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	12887733	EXPEDITED (15-DAY)		OT	CA-ROCHE-1696504		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported	
Arthritis; Chest Pain;	Arava			S	Unknown			Not Reported	
Condition Aggravated;	Enbrel			S	Unknown			Not Reported	
Fine Motor Skill	Apo-Hydroxyquine			S	Unknown			Not Reported	
Dysfunction; Gait	Methotrexate			S	Unknown			Not Reported	
Disturbance;	Hydroxychloroquine			S	Unknown			Not Reported	
Musculoskeletal Stiffness;	Sulfasalazine			S	Unknown			Not Reported	
Pain; Rheumatoid Arthritis	Prednisone			C				Not Reported	
	Ketorolac			C				Not Reported	
	Naproxen			C				Not Reported	

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Arthrotec
Xeljanz

C
C Oral

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	13058759	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015760		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	13659278	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170611422		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Janssen

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Drug	Simponi	S		Janssen
Intolerance; Joint Swelling;	Enbrel	S	Unknown	Not Reported
Joint Swelling; Multiple	Humira	S	Subcutaneous	Not Reported
Allergies; Musculoskeletal	Actemra	S	Subcutaneous	Not Reported
Pain; Psoriatic	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Arthropathy; Rash;				
Rheumatoid Arthritis;	Sulfasalazine	S	Unknown	Not Reported
Sciatica; Sinusitis;	Arava	S	Oral	Not Reported
Swelling; Swelling;	Gold	S	Unknown	Not Reported
Therapeutic Product Effect	Hydroxychloroquine	S	Unknown	Not Reported
Decreased; Therapeutic	Lyrica	S	Oral	Not Reported
Product Effect Incomplete;	Methotrexate Sodium	S	Unknown	Not Reported
Treatment Failure	Cellcept	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Pregabalin	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Actemra	S		Not Reported
	Actemra	S		Not Reported
	Azathioprine	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Ciclosporin	S	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cimzia	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Imuran /00001501/	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Mycophenolate Mofetil	S		Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	13976362	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018043		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	25 Mg, Q.Wk.		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	25 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	14128229	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020204		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort;	Leflunomide	S	Oral	20 Mg, Qd	Apotex
Adverse Drug Reaction;	Actemra	S	Unknown	Unk	Not Reported
Anti-Cyclic Citrullinated	Adalimumab	S	Subcutaneous	Unk	Not Reported
Peptide Antibody;	Enbrel	S	Subcutaneous	Unk	Not Reported
Contraindicated Product	Orencia	S	Unknown	Unk	Not Reported
Administered; Drug	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Ineffective; Joint Swelling;	Methotrexate	C	Subcutaneous	17.5 Mg, Unk	Not Reported
Leukopenia;	Methotrexate	C	Subcutaneous	15 Mg, Unk	Not Reported
Musculoskeletal Stiffness;	Methotrexate	C	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Pain; Rash; Rheumatoid	Sulfasalazine	C	Oral	1 G, Qd	Not Reported
Arthritis; Rheumatoid	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Factor Positive; Swelling;					
Toxicity To Various					
Agents; Visual Impairment					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	14633220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-003769		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
Arthralgia; Back Pain;	Actemra			S	Unknown	Unk		Not Reported
Condition Aggravated;	Arava			S	Unknown	20 Milligram, Qd		Not Reported
Drug Ineffective; Fatigue;	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
Incorrect Route Of Product	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
Administration; Joint	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported
Swelling; Loss Of	Methotrexate			S	Unknown	20 Milligram 4 Every 1 Week		Not Reported
Personal Independence In	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	200 Milligram, Bid		Not Reported
Daily Activities; Pain;	Winpred			S	Oral	5 Milligram, Qd		Not Reported
Peripheral Swelling;	Sulfasalazine			S	Unknown	1000 Milligram, Bid		Not Reported
Rheumatoid Arthritis	Apo-Prednisone			S	Oral	5 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Oral	200 Milligram, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	200 Unk	Not Reported
Prednisone	S	Oral	5 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
Etanercept	S	Subcutaneous	50 Milligram	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	14667263	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007994		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bronchitis; Contraindicated Product Administered; Depression; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Nodule; Off Label Use; Osteoporosis; Pain; Rheumatoid Arthritis; Stress	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Methotrexate			S	Oral	22.5 Mg, Q.Wk.		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	200 Mg, Bid		Not Reported
	Plaquenil /00072602/			C	Unknown	Unk		Not Reported
	Vitamin D /00107901/			C	Unknown	4000 Iu, Qd		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	4000 Iu, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	14784955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108888		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Contraindicated	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Administered;	Arava	S	Unknown	Not Reported
Drug Hypersensitivity;	Enbrel	S	Unknown	Not Reported
Drug Ineffective; Drug	Methotrexate Sodium	S	Unknown	Not Reported
Intolerance; Hepatitis;	Orencia	S	Unknown	Not Reported
Hypersensitivity; Red	Remicade	S	Intravenous (not	Not Reported
Blood Cell Sedimentation			otherwise specified)	
Rate Abnormal;	Sulfasalazine	S	Unknown	Not Reported
Rheumatoid Factor	Hydroxychloroquine	S	Unknown	Not Reported
Positive; Synovitis;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Vomiting	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Anakinra	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	14917260	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-043745			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Orencia			S	Intravenous (not	Unk		Bristol Myers Squibb	
Alopecia; Drug Ineffective;	Actemra			S	Unknown	Unk		Not Reported	
Glossodynia; Intentional	Arava			S	Oral	Unk		Not Reported	
Product Use Issue;	Arava			S	Unknown	Unk		Not Reported	
Maternal Exposure During	Reactine [Cetirizine			S	Unknown	Unk		Not Reported	
Pregnancy; Pain;	Hydrochloride]								
Pemphigus; Rheumatoid	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported	
Arthritis; Systemic Lupus	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
Erythematousus	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Cortisone Acetate			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Folic Acid	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Diclofenac	S	Unknown		Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	15291706	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015415739		45 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Malaise;	Enbrel			S	Subcutaneous	Unk Unk, Weekly		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Sulfasalazine	S	Unknown	Unk	Pfizer
	Sulfasalazine	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tylenol	C	Unknown	Unk	Not Reported
	Prednisone	C	Oral	10 Mg, 1x/Day	Not Reported
	Prednisone	C	Oral	6 Mg, 1x/Day	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Advil	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C		Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	16177041	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20190403869		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Paracetamol	S	Unknown	Dosage Form: Solution Subcutaneous	Johnson And Johnson
	Simponi	S	Subcutaneous		Not Reported
	Actemra	S	Subcutaneous		Not Reported
	Arava	S	Unknown		Not Reported
	Meloxicam	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	16323123	EXPEDITED (15-DAY)		OT	AR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-208121		57 YR	Female	ARG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
American Trypanosomiasis; Asthenia; Pyrexia	Prednisone			S	Unknown	40 Milligram, Daily		Mutual	
	Hydroxychloroquine			S	Unknown	Unk		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17261745	EXPEDITED (15-DAY)		OT	IL-GLAXOSMITHKLINE- IL2019EME238237			Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Benlysta			S		Unk		Glaxosmithkline	
	Prednisone			S		Unk		Not Reported	
	Plaquenil			S		Unk		Not Reported	
	Clexane			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17262610	EXPEDITED (15-DAY)		OT	PHHY2019GR210755		59 YR	Female	GRC

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Cough; Hyperparathyroidism Secondary; Osteoporosis; Pleuritic Pain; Rib Fracture; Upper Respiratory Tract Infection	Ramipril			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Lansoprazole			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk		Not Reported
	Metformin			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Exemestane			S	Unknown	Unk		Not Reported
	Thyroxin			S	Oral	Unk		Not Reported
	Dicumarol			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17265311	EXPEDITED (15-DAY)		OT	CA-ROCHE-2262233		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Inappropriate Schedule Of Product Administration; Joint Swelling; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal	Actemra			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 11 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Naproxen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17358352	EXPEDITED (15-DAY)	HO		CA-ROCHE-2532032		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diverticulitis; Drug Ineffective; Injection Site Urticaria; Nausea; Rash; Urticaria	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Atenolol			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17365297	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005932			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diclofenac	S	Unknown	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17369757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2538294			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Drug Ineffective; Hepatic	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported

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Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S			Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Solution	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17390099	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200153298			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Hypersensitivity; Psoriatic Arthropathy; Red Blood Cell Sedimentation Rate Increased	Simponi			S	Subcutaneous			Janssen	
	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Stelara			S	Subcutaneous			Janssen	
	Stelara			S	Subcutaneous			Janssen	
	Cimzia			S	Subcutaneous			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Otezla	S	Oral	Not Reported
	Otezla	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17423283	NON-EXPEDITED		OT	ES-LUPIN PHARMACEUTICALS INC.-2020-00169		51 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Porphyria Acute	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Lupin
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17433123	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM- 2020CA0805			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy;	Kineret			S	Subcutaneous			Not Reported
Contraindicated Product	Actemra			S	Subcutaneous	Not Specified		Not Reported
Administered; Drug	Arava			S	Oral			Not Reported
Ineffective; Ill-Defined	Cimzia Single-Use Prefilled			S	Subcutaneous	Solution		Not Reported
Disorder; Intentional	Syringe							
Product Use Issue; Loss	Enbrel			S	Unknown			Not Reported
Of Consciousness;	Humira			S	Subcutaneous	Solution		Not Reported
Mobility Decreased; Off	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Label Use								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Gold	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported
			Not Sepcified	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17433133	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0824		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Kineret			S	Unknown			Not Reported	
Arthralgia; Arthropathy;	Enbrel			S	Subcutaneous			Not Reported	
Condition Aggravated;	Enbrel			S	Unknown			Not Reported	
Deformity; Diarrhoea;	Enbrel			S	Unknown			Not Reported	
Disease Progression;	Humira			S	Subcutaneous			Not Reported	
Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Interaction; Embolism;	Methotrexate			S	Unknown			Not Reported	
Fear; Fine Motor Skill	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Dysfunction; Finger	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
Deformity; Hand	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Deformity; Impaired	Apo-Warfarin			S	Unknown			Not Reported	
Healing; Joint Swelling;									
Musculoskeletal Disorder;									
Musculoskeletal Stiffness;									
Nausea; Off Label Use;									
Pain; Rash; Rheumatoid									
Arthritis; Swelling;									
Therapeutic Product Effect									
Decreased; Therapeutic									

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Product Effect Incomplete	Celebrex	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin	S	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17450609	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007837		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Ineffective; Thrombosis	Hydroxychloroquine			S	Unknown	200 Mg, Q.12h		Apotex	
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex	
	Methotrexate			S	Oral	15 Mg, Q.Wk.		Not Reported	
	Sulfasalazine			C	Unknown	1000 Mg, Bid		Not Reported	
	Sulfasalazine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17557584	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200318937		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Muscle Spasms; Rheumatoid Arthritis	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Acetaminophen W/Oxycodone			C	Unknown			Not Reported	

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Hydrochloride			
Folic Acid	C	Unknown	Not Reported
Thiamine Hydrochloride	C		Not Reported
Oxycodone Terephthalate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17656097	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA080271		71 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate			S	Other	600 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	1000 Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi
	Lovenox			S	Subcutaneous	0.6 MI, Qd		Sanofi
	Lovenox			S				Sanofi
	Paracetamol			S	Other	4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C	Other	2 Df, Qd		Not Reported
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Lasilix [Furosemide]			C	Parenteral	40 Mg, Qd		Not Reported
	Lantus			C	Subcutaneous	20 Iu, Qd		Not Reported
	Pantoprazole			C	Oral	40 Mg, Qd		Not Reported
	Pantoprazole			C				Not Reported
	Pantoprazole			C				Not Reported
	Tienam			C	Intravenous (not otherwise specified)	1 G, Q8h		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17671014	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-031107		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cough; Dyspnoea; Oropharyngeal Pain; Painful Respiration	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb	
	Prednisone			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17692947	EXPEDITED (15-DAY)		OT	FR-ADVANS PHARMA- 202004002601			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Respiratory Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia	
	Ceftriaxone			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17702980	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020- 012108			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported	
	Erythromycin			S	Unknown			Bausch And Lomb	
	Erythromycin			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
	Ceclor			S	Unknown			Not Reported	
	Celebrex			S	Oral			Not Reported	

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	Demerol	S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Norfloxacin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arthrotec	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Meperidine Hydrochloride	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726376	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588721			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726381	EXPEDITED (15-DAY)		HO, OT	GB-ADVANZ PHARMA-GSH201806-002096			Unknown	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Altered State Of Consciousness; Decreased Appetite; Headache; Hypoglycaemia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia	
	Hydroxychloroquine			S				Concordia	
	Cellcept			C		500 Mg, Bid		Not Reported	
	Alfacalcidol			C				Not Reported	
	Amlodipine			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Atenolol			C		50 Mg, Freq: Unk X 1 Days		Not Reported	
	Prednisolone			C		10 Mg, Freq: Unk X 1 Days		Not Reported	
	Furosemide			C				Not Reported	
	Calcium Carbonate			C				Not Reported	
Icodextrin			C				Not Reported		
Dianeal			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726434	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245618		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour ()		Sun	
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726480	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA- E2B_00007901			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Cardiac Arrest; Electrocardiogram Qt Prolonged; Electrocardiogram U Wave Present;	Hydroxychloroquine			S	Unknown	60 Tablets, 1200 Mg Total Dose		Concordia	
	Oxycodone, Paracetamol			S	Unknown	35 Tablets (5/325 Mg)35 Dosage Form Total		Not Reported	

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Hypokalaemia;
Hypomagnesaemia;
Hypotension; Intentional
Overdose; Overdose;
Somnolence; Torsade De
Pointes; Ventricular
Fibrillation

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726496	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590320			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726545	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589092			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cetirizine;Pseudoephedrine			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726564	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589944			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; Herpes Zoster; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Naproxen			C				Not Reported
	Lyrica			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590207			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Drug Ineffective;	Actemra	S	Subcutaneous	Not Reported
Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Lipitor	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726709	EXPEDITED (15-DAY)		DE, OT	FR-ADVANZ PHARMA-202004004067			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Off Label Use; Septic Shock	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726710	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589755			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726929	EXPEDITED (15-DAY)		LT, OT	FR-ADVANTZ PHARMA-202004004141			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd Film-Coated Tablet		Concordia	
	Hydroxychloroquine			S				Concordia	
	Amoxicillin Clavulanic Acid			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726980	EXPEDITED (15-DAY)		OT	NL-ACCORD-071584		60 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Toxicity; Treatment Failure	Methotrexate			S				Accord	
	Prednisone			C				Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Azathioprine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727035	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020168024		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	

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Prolonged; Off Label Use; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020167372		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Pr Prolongation; Electrocardiogram T Wave Inversion; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727049	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017786		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Herpes Zoster	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727077	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589398		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported

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Mobility Decreased; Product Dose Omission; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Restasis	C	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported
	Synthroid	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727131	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589814			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown	Tablet (Extendedrelease		Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727217	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3384129-00		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Atrial Flutter; Cardio-Respiratory Arrest	Kaletra 200/50	S	Oral	Not Reported
	Kaletra 200/50	S		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Azithromycin	S	Oral	Not Reported
	Dolquine	S	Oral	Not Reported
	Dolquine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727313	EXPEDITED (15-DAY)		OT	US-ADVANTZ PHARMA-GSH201902-000459			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscular Weakness; Neuromyopathy; Weight Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd		Concordia	
	Losartan			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588915			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727336	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034554			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cortisone Acetate			S	Topical	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Phthalylsulphathiazole			S	Unknown	Unk		Not Reported
	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rituximab	S	otherwise specified) Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727348	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034905			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram, Qwk		Not Reported
	Apo-Prednisone			S	Unknown	1 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Azathioprine			S	Oral	200 Milligram, Qd		Not Reported
	Depo-Medrol With Lidocaine			S	Intra-articular			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram, Qd		Not Reported
	Ketoprofen			S	Topical	Unk, Qid		Not Reported
	Leucovorin Calcium			S	Unknown	1 Dosage Form, Qwk		Not Reported
	Methotrexate			S	Subcutaneous	15 Milligram, Qwk		Not Reported
	Methotrexate			S	Oral	15 Unk		Not Reported
	Prevnar 13			S	Intramuscular	0.5 Milligram, Total		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727372	EXPEDITED (15-DAY)		HO	FR-SA-2020SA111792		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaemia; Off Label Use	Plaquenil	S	Oral	600 Mg, Qd	Sanofi
	Plaquenil	S			Sanofi
	Doliprane	S	Oral	4000 Mg, Qd	Not Reported
	Lovenox	S	Subcutaneous	1 Df, Qd	Sanofi
	Azithromycin	S	Oral	1 Df, Qd	Not Reported
	Kaleorid Lp	C	Oral	3 Df, Qd	Not Reported
	Metformin Almus	C	Oral	Unk	Not Reported
	Gliclazide Arrow	C	Oral		Not Reported
	Atorvastatin Arrow	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727386	EXPEDITED (15-DAY)		OT	IT-ACCORD-180018		43 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Tacrolimus			S				Accord
	Mycophenolic Acid			S				Not Reported
	Hydroxychloroquine			S		400 Mg, Qd		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported
	Methylprednisolone			C		Unk (Pulses)		Not Reported
	Immunoglobulins (Ivig)			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported
	Prednisone			S		Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S		25 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unk (50 Mg Qd, Tapering Dose)	Not Reported
Prednisone	S	Unk Unk (7.5 Mg Qd, Dose Tapering)	Not Reported
Prednisone	S	Unk (25 Mg Qd, Dose Tapering)	Not Reported
Prednisone	S	15 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728025	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-033863			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Diclofenac Sodium			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Folic Acid			S	Unknown	Unk		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi			S		Subcutaneous		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Apr-2020	17728040	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034901			Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Orencia			S	Unknown	Unk		Bristol Myers Squibb		
	Apo-Leflunomide			S	Unknown	Unk		Not Reported		
	Cimzia			S	Subcutaneous	Unk		Not Reported		
	Enbrel			S	Unknown	Unk		Not Reported		
	Humira			S	Subcutaneous	40 Milligram		Not Reported		
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported		
	Methotrexate			S	Subcutaneous	Unk		Not Reported		
	Methotrexate			S	Oral	Unk		Not Reported		
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported		
	Simponi			S	Subcutaneous	Unk		Not Reported		
	Sulfasalazine			S	Unknown	Unk		Not Reported		
	Tocilizumab			S	Unknown	Unk		Not Reported		
	Tofacitinib			S	Unknown	Unk		Not Reported		
	Xeljanz			S	Unknown	Unk		Not Reported		
	Rabeprazole Sodium			C	Oral	20 Milligram, Every 14 Hours		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Apr-2020	17728203	EXPEDITED (15-DAY)		HO	MX-TEVA-2020-MX- 1231149		29 YR	Female	MEX	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Brain Abscess; Endophthalmitis; Liver Abscess; Muscle Abscess;	Mycophenolate Mofetil			S	Oral	2.5 Gram Daily; Scheduled For 2 Months		Teva		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nocardiosis; Perinephric Abscess; Pyomyositis	Prednisone	S	Oral	30 Milligram Daily; Scheduled For 2 Months	Not Reported
	Hydroxychloroquine	S	Oral	200 Milligram Daily; Scheduled For 2 Months	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728379	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2020AMR072153			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Burning Sensation; Muscle Spasms	Benlysta			S	Unknown	Unk		Glaxosmithkline
	Plaquenil (Hydroxychloroquine)			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728437	EXPEDITED (15-DAY)		CA	DE-TEVA-2020-DE- 1228290			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Talipes	Prednisolone			S	Transplacental			Actavis
	Hydroxychloroquine			S	Transplacental			Teva
	Certolizumab			S	Transplacental			Not Reported
	Sulfasalazine			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728554	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1228769			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Exposure During Pregnancy; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cimzia	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous Powder For Solution For Pre-Filled Syringe	Not Reported
Tocilizumab	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728562	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228718			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazol	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728575	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1228801			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Alendronate Sodium			S	Unknown			Actavis
Alopecia; Arthropathy;	Diclofenac Sodium			S	Unknown			Actavis
Contraindicated Product	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr
Administered; Discomfort;	Prednisone			S	Unknown			Actavis
Drug Ineffective; Fatigue;	Actemra			S	Unknown			Not Reported
Glossodynia; Hand	Arava			S	Oral			Not Reported
Deformity; Infusion	Cetirizine Hydrochloride			S	Unknown			Not Reported
Related Reaction;	Cimzia			S	Subcutaneous			Not Reported
Maternal Exposure During	Cortisone Acetate			S	Unknown			Not Reported
Pregnancy; Pain;	Desoximetasone			S	Oral			Not Reported
Pemphigus; Product Use	Enbrel			S	Subcutaneous			Not Reported
Issue; Rash; Rheumatoid	Folic Acid			S	Unknown			Not Reported
Arthritis; Swelling;	Humira			S	Subcutaneous			Not Reported
Systemic Lupus	Hydroxychloroquine			S	Oral			Not Reported
Erythematous; Treatment	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
Failure; Wound	Hydroxychloroquine Phosphate			S	Unknown	400 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown 2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728607	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1228759		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Anti-Cyclic	Acetaminophen			S	Unknown			Not Reported
Citrullinated Peptide	Diclofenac Sodium			S	Unknown			Actavis
Antibody Positive;	Leflunomide			S	Oral			Barr
Arthropathy; Condition	Methotrexate			S	Unknown			Barr
Aggravated; Discomfort;	Methotrexate			S	Unknown			Barr
Drug Ineffective; Drug	Prednisone			S	Unknown			Actavis
Intolerance; Duodenal	Prednisone			S	Unknown			Actavis
Ulcer Perforation; Fatigue;	Actemra			S	Subcutaneous			Not Reported
Glossodynia; Hand	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Deformity; Hepatic	Apo Prednison			S	Unknown			Not Reported
Enzyme Increased;	Arava			S	Oral			Not Reported
Hypersensitivity; Infusion	Arava			S	Oral			Not Reported
Related Reaction;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Intentional Product Use	Cetirizine Hydrochloride			S	Unknown			Not Reported
Issue; Joint Swelling; Live								
Birth; Maternal Exposure								
During Pregnancy; Off								
Label Use; Pain;								
Pemphigus; Pericarditis;								
Rash; Rheumatoid								
Arthritis; Rheumatoid								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Oral		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	40 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram Daily;	Not Reported
	Methotrexate	S	Oral	25 Milligram Daily;	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Oral	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown	40 Milligram Daily;	Not Reported
Plaquenil	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
Remicade	S	Endocervical		Not Reported
Remicade	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Intravenous (not otherwise specified)		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	1 Gram Daily;	Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Oral		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported

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Xeljanz	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728614	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034852		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Drug Ineffective; General Physical Health Deterioration; Headache; Hypersensitivity; Hypertension; Joint Swelling; Maternal Exposure During Pregnancy; Musculoskeletal Stiffness; Pain; Pemphigus; Pericarditis; Rheumatic Fever; Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased; Synovitis; Systemic Lupus Erythematous; Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	400 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Cortisone Acetate			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Diclofenac			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Folic Acid			S	Unknown	5 Milligram		Not Reported
	Fosamax			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	400 Milligram, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Salazopyrine	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Unknown	20 Milligram, Qwk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729022	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020141193		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Gait Disturbance; Hypoaesthesia; Joint Swelling; Muscular Weakness; Nerve Injury; Off Label Use; Pain; Product Use Issue; Sciatica; Spinal Stenosis	Methotrexate Sodium			S				Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Sulfasalazine			S	Unknown	2 G, Q Unk		Pfizer
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer
	Plaquenil			S	Unknown	400 Mg, Q Unk		Not Reported
	Plaquenil			S		400 Mg, 1x/Day		Not Reported
	Actonel Xr			C	Unknown	75 Mg Q Unk		Not Reported
	Baclofen			C	Unknown	10 Mg, Daily At Night (Qhs)		Not Reported
	Folic Acid			C	Unknown	5 Mg, 1x/Day		Not Reported
	Lyrica			C	Unknown	75 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	7.5 Mg, 1x/Day		Not Reported
	Vitamin D			C	Unknown	2000 Iu, Daily		Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729036	NON-EXPEDITED			GR-LUPIN PHARMACEUTICALS INC.-2020-00627		40 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	Unk		Lupin	
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported	
	Prednisolone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729108	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017788		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pulmonary Mass; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	200 Milligram, Unk		Not Reported	
	Enbrel			S		Unk		Not Reported	
	Gold			S		Unk		Not Reported	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	
	Methotrexate			S		Unk		Not Reported	
	Prednisone			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729119	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1228814			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain;	Diclofenac Sodium			S	Unknown			Actavis	
	Diclofenac Sodium			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	

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Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Arava	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Cortisone Aceta	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729176	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228816		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthralgia; Blood	Diclofenac			S	Unknown			Actavis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cholesterol Increased;	Methotrexate	S	Unknown	Barr
Contraindicated Product	Methotrexate	S	Subcutaneous	Barr
Administered; Drug	Prednisone	S	Unknown	Actavis
Ineffective; General	Cetirizine Hydrochloride	S	Unknown	Not Reported
Physical Health	Actemra	S	Unknown	Not Reported
Deterioration; Headache;	Arava	S	Unknown	Not Reported
Hypersensitivity;	Apo Prednison	S	Unknown	Not Reported
Hypertension; Joint	Cimzia Single-Use Prefilled	S	Unknown	Not Reported
Swelling; Maternal	Syringe	S	Unknown	Not Reported
Exposure During	Cimzia Single-Use Prefilled	S	Subcutaneous	Not Reported
Pregnancy;	Syringe	S	Subcutaneous	Not Reported
Musculoskeletal Stiffness;	Desoximetasone	S	Oral	Not Reported
Pain; Pemphigus;	Enbrel	S	Subcutaneous	Not Reported
Pericarditis; Product Use	Folic Acid	S	Unknown	Not Reported
Issue; Rheumatic Fever;	Fosamax	S	Unknown	Not Reported
Rheumatoid Arthritis;	Humira	S	Subcutaneous	Not Reported
Swelling; Swollen Joint	Methotrexate	S	Oral	Not Reported
Count Increased;	Orencia	S	Unknown	Not Reported
Synovitis; Systemic Lupus	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Erythematosis;	Pseudoephedrine Hcl	S	Unknown	Not Reported
Therapeutic Product Effect	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Decreased; Treatment	Simponi	S	Subcutaneous	Not Reported
Failure; Type 2 Diabetes	Sulfasalazine	S	Oral	Not Reported
Mellitus	Xeljanz	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
			400 Milligram Daily;	

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Rituxan	S	Unknown	Not Reported
Salazopyrine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729197	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202004240		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Sudden Death	Propofol (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported	
	Salbutamol			S	Respiratory (inhalation)			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Metoclopramide Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Ipratropium Bromide			C	Respiratory (inhalation)			Not Reported	
	Enoxaparin Sodium			C	Subcutaneous			Not Reported	
	Cefotaxime			C	Intravenous drip			Not Reported	
	Midazolam			C	Intravenous drip			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729226	EXPEDITED (15-DAY)		HO	NVSC2020IN115852		29 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Dysphagia; Mouth Ulceration; Ocular Hyperaemia; Product Use In Unapproved Indication; Skin Exfoliation; Toxic Epidermal Necrolysis	Hydroxychloroquine			S	Unknown	100 Mg, Bid		Novartis	
	Mycophenolate Mofetil			C	Unknown	1.5 G, Bid		Not Reported	
	Prednisolone			C	Unknown	30 Mg, Qd		Not Reported	
	Prednisolone			C	Unknown	60 Mg, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729374	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA- 2020VAL000340			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown	Unk		Validus
	Meperidine Hydrochloride			S	Unknown	Unk		Validus
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celecoxib			S	Oral	200 Mg, Qd (1 Df, Every 1 Day)		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Levofloxacin			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	400 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729461	EXPEDITED (15-DAY)		OT	NVSC2020IN115930		51 YR	Female	IND

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Product Use In Unapproved Indication; Tinnitus	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Novartis	
	Prednisolone			C	Unknown	40 Mg, Qd (Gradual Taper To 5 Mg/Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1228819			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Exposure During Pregnancy; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Diclofenac Sodium			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Phthalylsulfathiazole			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729492	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228815			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Meloxicam			S	Unknown			Not Reported
Abdominal Discomfort;	Methotrexate			S	Intravenous (not otherwise specified)			Barr
Antinuclear Antibody Positive; Arthralgia;	Prednisone			S	Unknown			Actavis
Arthritis; Blister; Dry Mouth; Headache;	Celebrex			S	Unknown			Not Reported
Hypersensitivity Vasculitis;	Arava			S	Unknown			Not Reported
Hypoaesthesia; Joint Swelling; Leukopenia; Lip Swelling;	Belimumab			S	Unknown			Not Reported
Lymphadenopathy;	Breo Ellipta			S	Respiratory (inhalation)			Not Reported
Menorrhagia;	Colchicine			S	Unknown			Not Reported
Musculoskeletal Stiffness; Myalgia; Nausea; Parotid Gland Enlargement;	Dexilant			S	Oral	60 Milligram Daily;		Not Reported
Peripheral Swelling;	Estrogel			S	Topical			Not Reported
Rheumatoid Arthritis;	Methotrexate			S	Oral			Not Reported
Sjogren'S Syndrome;	Plaquenil			S	Unknown	400 Milligram Daily;		Not Reported
Systemic Lupus Erythematosus; Vasculitis	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ventolin Hfa			S	Respiratory (inhalation)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729669	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020171686		65 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Off Label Use; Product Use In Unapproved Indication;	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
Tachyarrhythmia	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Tocilizumab			C	Intravenous (not	Unk		Not Reported

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Ceftriaxon	C	otherwise specified) Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729787	EXPEDITED (15-DAY)		HO	ES-PFIZER INC- 2020171239		53 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use Issue; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Dolquine			S				Not Reported
	Propofol			S	Intravenous (not otherwise specified)	6.6 Mg/Kg Every Hour		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729799	EXPEDITED (15-DAY)		LT	FR-PFIZER INC- 2020171243		59 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine Hcl			S	Oral	225 Mg, 1x/Day		Pfizer
	Loxapine			S	Oral	155 Mg, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Theralene			S	Oral	50 Mg, 1x/Day		Not Reported
	Paracetamol			C	Oral	1 G, 1x/Day		Not Reported
	Akineton [Biperiden Hydrochloride]			C	Oral	4 Mg		Not Reported
	Macrogol 4000			C	Oral	Unk		Not Reported
	Atorvastatin			C	Oral	40 Mg, 1x/Day		Not Reported
	Ezetimibe			C	Oral	10 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Kardegic	C	Oral	75 Mg, 1x/Day	Not Reported
	Nebivolol	C	Oral	7.5 Mg, 1x/Day	Not Reported
	Ramipril	C	Oral	1.25 Mg, 1x/Day	Not Reported
	Diazepam	C	Oral	10 Mg, 1x/Day	Not Reported
	Nicopatch	C	Transdermal	7 Mg, 1x/Day	Not Reported
	Nicotine	C	Oral	12 Mg, 1x/Day	Not Reported
	Zopiclone	C	Oral	7.5 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729811	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020171785		21 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Linezolid			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Ambisome [Amphotericin B]			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729886	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020171246		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Effexor Lp			S	Oral	150 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Risperidone			S	Oral	2 Mg, 1x/Day		Not Reported	
	Acebutolol Hydrochloride			C	Oral	400 Mg, 1x/Day		Not Reported	
	Oxazepam			C	Oral	100 Mg, 1x/Day		Not Reported	
	Sodium Enoxaparin			C	Subcutaneous	4000 Iu, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Macrogol 4000	C	Oral	2 Df, 1x/Day	Not Reported
Amlodipine	C	Oral	10 Mg, 1x/Day	Not Reported
Clomipramine Hydrochloride	C	Oral	150 Mg, Monthly	Not Reported
Zopiclone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Nicardipine Hydrochloride	C	Oral	60 Mg, 1x/Day	Not Reported
Hydrochlorothiazide	C	Oral	25 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729999	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017804		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram,Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Orencia			S		125 Milligram, Weekly (Qw)		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			C	Subcutaneous	50 Milligram, Monthly (Qm)		Not Reported
	Sulfasalazine			C				Not Reported
	Prednisone			C				Not Reported
	Leflunomide			C				Not Reported
	Xeljanz			C	Oral	5mg 2every 1day		Not Reported
	Arava			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730004	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1228746			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Acetaminophen			S	Unknown			Not Reported
Alopecia; Anti-Cyclic	Diclofenac Sodium			S	Unknown			Actavis
Citrullinated Peptide	Leflunomide			S	Unknown			Barr
Antibody Positive;	Methotrexate			S	Unknown			Barr
Condition Aggravated;	Methotrexate			S				Barr
Discomfort; Drug	Prednisone			S	Unknown			Actavis
Ineffective; Drug	Actemra			S	Unknown			Not Reported
Intolerance; Fatigue;	Actemra			S	Unknown			Not Reported
Glossodynia; Hand	Arava			S	Oral			Not Reported
Deformity; Hepatic	Apo-Prednisone			S	Unknown			Not Reported
Enzyme Increased; Hip	Cetirizine Hydrochloride			S	Unknown			Not Reported
Arthroplasty;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Hypersensitivity; Infusion	Cetirizine			S	Unknown			Not Reported
Related Reaction; Joint	Hydrochloride/Pseudoephedrine							
Swelling; Knee	Hydrochloride							
Arthroplasty; Maternal	Cimzia			S	Subcutaneous			Not Reported
Exposure During	Cortisone Acetate			S	Oral			Not Reported
Pregnancy; Pain;	Cortisone Acetate			S	Unknown			Not Reported
Pemphigus; Pericarditis;	Cortisone Acetate			S	Unknown			Not Reported
Rash; Rheumatoid	Desoximetasone			S	Oral			Not Reported
Arthritis; Rheumatoid	Desoximetasone			S				Not Reported
Factor Positive; Swelling;	Enbrel			S	Subcutaneous			Not Reported
Synovitis; Systemic Lupus	Folic Acid			S	Unknown			Not Reported
Erythematous; Treatment	Folic Acid			S	Oral			Not Reported
Failure; Wound	Fosamax			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Golimumab			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram Daily;	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine (Cetirizine)	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Topicort	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C			Not Reported
Salazopyrina	C			Not Reported
Tofacitinib Citrate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590432		34 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Drug Ineffective; Dyspepsia; General Physical Health Deterioration; Nausea; Sleep Disorder	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Otezla			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ustekinumab			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Orencia			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730396	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590228			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia;	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hand Deformity; Joint Range Of Motion	Leflunomide	S	Unknown	Not Reported
Decreased; Joint Swelling;	Meloxicam	S	Unknown	Not Reported
Malaise; Mobility	Methotrexate	S	Unknown	Not Reported
Decreased; Muscular Weakness;	Mobicox	S	Unknown	Not Reported
Musculoskeletal Pain;	Orencia	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Depomedrol	C	Intramuscular	Not Reported
Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Diclofenac	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730403	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012547			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown			Not Reported
Alopecia; Arthropathy;	Desoximetasone			S	Oral			Not Reported
Contraindicated Product Administered; Discomfort;	Adalimumab			S	Subcutaneous			Not Reported
Drug Ineffective; Fatigue;	Apo-Prednisone			S	Unknown			Not Reported
Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use;	Arava			S	Oral			Not Reported
Pain; Pemphigus; Product Use Issue; Rash;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Rheumatoid Arthritis;	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil (Hydroxychloroquine Phosphate)	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	In Pre-Filled Syringe
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730404	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012542		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac			S	Unknown			Not Reported
Alopecia; Arthralgia; Blood Cholesterol Increased;	Desoximetasone			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Contraindicated Product	Actemra	S	Unknown		Not Reported
Administered; Drug	Apo Prednison	S	Unknown		Not Reported
Ineffective; General	Arava	S	Unknown		Not Reported
Physical Health	Cetirizine Hydrochloride	S	Unknown		Not Reported
Deterioration; Headache;	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
Hypersensitivity;	Cimzia	S	Unknown	Single-Use Prefilled Syringe	Not Reported
Hypertension; Joint Swelling; Maternal Exposure During Pregnancy;	Enbrel	S	Subcutaneous		Not Reported
Musculoskeletal Stiffness; Pain; Pemphigus;	Folic Acid	S	Unknown		Not Reported
Pericarditis; Product Use Issue; Rheumatic Fever; Rheumatoid Arthritis;	Fosamax	S	Unknown		Not Reported
Swelling; Swollen Joint Count Increased;	Humira	S	Subcutaneous		Not Reported
Synovitis; Systemic Lupus Erythematosus;	Hydroxychloroquin	S	Unknown		Not Reported
Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednison	S	Unknown		Not Reported
	Pseudoephedrine Hcl	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Unknown		Not Reported
	Salazopyrine	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfathalidine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590245		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Injury; Lymphadenectomy; Malignant Melanoma; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous drip	365.0		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	731.0		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown	Emulsion		Not Reported
	Synthroid			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730976	EXPEDITED (15-DAY)		HO	CA-ROCHE-2588779		77 YR	Male	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	11720121	EXPEDITED (15-DAY)		DS	CA-ROCHE-1657676			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Oral						Not Reported
	Hydroxychloroquine	S	Oral						Not Reported
	Methotrexate	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	12454121	EXPEDITED (15-DAY)		OT	CA-ROCHE-1771508		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Limb Discomfort; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Plaquenil (Hydroxychloroquine Sulfate)		Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 190 Days		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Estradiol			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic	Solution Ophthalmic		Not Reported
	Cosopt			C	Unknown	Eye Drops		Not Reported
	Furosemide			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

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Gravol Ginger	C			Not Reported
Zingiber Officinale	C			Not Reported
Estrogel	C			Not Reported
Calcium	C	Unknown		Not Reported
Potassium Chloride	C	Unknown		Not Reported
Morphine	C	Unknown	As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	12844829	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1042716		66 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Atrial Flutter; Drug Interaction	Methotrexate			S		7.5 Mg, Cycle (10 Days)		Not Reported
	Methotrexate			S		15 Mg, Qw		Not Reported
	Hydroxychloroquine			S		200 Mg, Qd		Not Reported
	Certolizumab Pegol			S		200 Mg, Biweekly		Mylan
	Certolizumab Pegol			S		1 Df, Q21d		Mylan
	Bromazepam			C		Unk		Mylan
	Bromazepam			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	13006742	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP015239		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Alendronate			S				Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Administered; Drug	Apo-Leflunomide	S	Unknown	20 Mg, Unk	Apotex
Eruption; Drug	Apo-Leflunomide	S	Oral	Unk	Apotex
Hypersensitivity; Drug	Leflunomide	S	Unknown	Unk	Apotex
Ineffective; Drug	Leflunomide	S	Oral	Unk	Apotex
Intolerance; Drug	Leflunomide	S	Oral	Unk	Apotex
Tolerance Decreased;	Leflunomide	S	Unknown	20 Mg, Unk	Apotex
Erythema; Gastric	Leflunomide	S	Oral	Unk	Apotex
Disorder; Granuloma Skin;	Leflunomide	S	Oral	Unk	Apotex
Hypercalcaemia;	Leflunomide	S	Oral	20 Mg, Unk	Apotex
Hypersensitivity;	Codeine	S	Unknown	Unk	Not Reported
Inflammation; Infusion	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
Related Reaction; Loss Of	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Personal Independence In	Enbrel	S	Unknown	25 Mg, Q.Wk.	Not Reported
Daily Activities;	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
Musculoskeletal Stiffness;	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Off Label Use; Pain;	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
Panniculitis; Peripheral	Enbrel	S	Unknown	25 Mg, B.I.Wk.	Not Reported
Swelling; Product Use	Humira	S	Subcutaneous	40 Mg, Unk, Cyclical	Not Reported
Issue; Rash; Rash Pruritic;	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Week	Not Reported
Red Blood Cell	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Sedimentation Rate	Methotrexate Sodium	S	Oral	10 Mg, Q.Wk.	Not Reported
Increased; Rheumatoid	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Arthritis; Rheumatoid	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
Nodule; Skin Necrosis;	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
Skin Ulcer; Therapeutic	Methotrexate Sodium	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
Product Effect Decreased;	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Therapeutic Product Effect	Methotrexate Sodium	S	Unknown	12 Mg, Q.Wk.	Not Reported
Incomplete; Therapeutic	Methotrexate Sodium	S	Unknown	10 Mg, Q.Wk.	Not Reported
Response Decreased;	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
Ulcer	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
	Orencia	S	Intravenous (not	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Orencia	S	Unknown	760 Mg, Q.Wk.	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk (Therapy Duration 365 Unspecified Unit)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
Tocilizumab	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	360 Mg, Unk	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	2.68 Mg, 1 Every 4 Weeks	Not Reported
Actemra	S	Unknown	680 Mg, Q.M.T.	Not Reported
Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Oral	10 Mg, 1 Every 4 Weeks	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
Sulfasalazin	S	Unknown	500 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazin	S	Unknown	Unk	Not Reported
Myochrysine	S	Parenteral	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	25 Mg, Q.Wk.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Unk	Not Reported
Adalimumab	S	Subcutaneous	40 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	70 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Subcutaneous	10 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	15 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12.5 Mg, 1 Every 4 Weeks	Not Reported
Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	12 Mg, Unk	Not Reported
Alendronic Acid	S	Unknown	70 Mg, Q.Wk.	Not Reported
Arava	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Infliximab	S	Intravenous (not	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Simponi	S	Unknown	360 Mg, Q.M.T.		Not Reported
Simponi	S	Subcutaneous	680 Mg, Q.M.T.		Not Reported
Etanercept	S	Unknown	50 Mg, Q.Wk.		Not Reported
Etanercept	S	Unknown	25 Mg, Unk		Not Reported
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd		Not Reported
Prednisone	C	Unknown	10 Mg, Qd		Not Reported
Prednisone	C	Unknown	10 Mg, Qd		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz	C	Oral	5 Mg, Bid		Not Reported
Xeljanz	C	Unknown	5 Mg, Bid		Not Reported
Alendronate Sodium	C	Subcutaneous	70 Mg, Q.Wk.		Not Reported
Sulfasalazine	C	Unknown	Unk		Not Reported
Prednisolone	C	Unknown	10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	13216626	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890689		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	13359948	EXPEDITED (15-DAY)		OT	CA-SA-2017SA042969		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S	Oral	Unk Unk, Qw		Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk		Sanofi
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Qw		Not Reported
	Actemra			S		640 Unk		Not Reported
	Actemra			S		640 Unk		Not Reported
	Apo-Cyclosporine			S	Oral	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg,Qw		Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Other	50 Mg, 1 In 1 Week		Not Reported
	Enbrel			S		50 Unk		Not Reported
	Enbrel			S		50 Mg For 4 Yrs		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Humira			S		40 Unk		Not Reported
Humira			S		40 Mg, Qw For 4 Years		Not Reported	
Apo-Azathioprine			S	Unknown	Unk Unk,Unk		Not Reported	
Remicade			S	Intravenous (not otherwise specified)	300 Mg		Not Reported	

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Certolizumab	S	Subcutaneous	200 Mg, Qw	Not Reported
Certolizumab	S		200 Unk	Not Reported
Certolizumab	S		200 Mg For 9.0 Month(S) Unk	Not Reported
Gold	S	Unknown	Unk Unk, Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw	Not Reported
Infliximab	S		300 Mg, Qw For 2 Years	Not Reported
Methotrexate Sodium	S	Unknown	Unk Unk, Unk	Not Reported
Rituximab	S	Unknown	Unk Unk, Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Unk	Not Reported
Simponi	S	Unknown	Unk Unk, Unk	Not Reported
Azathioprine	S	Unknown		Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Prednisone	C			Not Reported
Piroxicam	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	13657150	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA105823		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
Arthropathy; C-Reactive	Sodium Aurothiomalate			S	Parenteral	Unk Unk,Unk		Not Reported
Protein Abnormal;	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
Contraindicated Product	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
Administered; Deep Vein	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
Thrombosis; Diverticulitis;	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
Drug Hypersensitivity;	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
Drug Ineffective; Drug	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
Intolerance; Feeling	Hydroxychloroquine			S		Unk Unk,Unk		Sanofi
Abnormal; Haemoglobin	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
Decreased; Herpes	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
Zoster; Intentional Product	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
Use Issue; Interstitial Lung								
Disease; Joint								

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Arthroplasty; Joint Swelling; Knee	Leflunomide	S	Oral	Unk Unk,Unk	Sanofi
Arthroplasty; Myocardial Infarction; Off Label Use;	Minocycline Hydrochloride	S			Not Reported
Pain; Photosensitivity	Minocycline Hydrochloride	S			Not Reported
Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Methotrexate	S			Not Reported
Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Methotrexate	S	Intra-arterial		Not Reported
	Arava	S			Sanofi
	Arava	S			Sanofi
	Leflunomide	S			Sanofi
	Leflunomide	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Plaquenil	S			Sanofi
	Plaquenil	S		400 Mg	Sanofi
	Oxycodone	S		10 Mg	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk,Unk	Not Reported
	Humira	S		Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Remicade	S		Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk,Unk	Not Reported

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Enbrel	S		Unk Unk,Unk	Not Reported
Marijuana	S			Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Gold	S			Not Reported
Ilaris	S	Subcutaneous	Unk Unk,Unk	Not Reported
Ilaris	S	Subcutaneous	Unk Unk,Unk	Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk Unk,Unk	Not Reported
Rituximab	C		Unk	Not Reported
Anakinra	C		Unk	Not Reported
Lyrica	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	13868474	EXPEDITED (15-DAY)		OT	CA-ROCHE-1976526		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730.0 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	15388757	EXPEDITED (15-DAY)		OT	CA-ROCHE-2182492		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Rituxan			S	Intravenous (not			Not Reported	
Adverse Drug Reaction;					otherwise specified)				
Adverse Event; Alopecia;	Actemra			S	Intravenous (not			Not Reported	
Anti-Cyclic Citrullinated					otherwise specified)				
Peptide Antibody Positive;	Enbrel			S	Subcutaneous			Not Reported	
Arthropathy; Condition									
Aggravated; Discomfort;	Methotrexate			S	Oral			Not Reported	
Drug Ineffective; Drug									
Intolerance; Fatigue;	Methotrexate			S	Unknown			Not Reported	
Glossodynia; Hand									
Deformity; Hepatic	Methotrexate			S	Unknown			Not Reported	
Enzyme Increased; Hip	Sulfasalazine			S	Oral			Not Reported	
Arthroplasty;									
Hypersensitivity; Infusion	Sulfasalazine			S	Unknown			Not Reported	
Related Reaction; Joint									
Swelling; Knee	Apo-Prednisone			S	Unknown			Not Reported	
Arthroplasty; Maternal									
Exposure During	Apo-Prednisone			S	Unknown			Not Reported	
Pregnancy; Pain;	Remicade			S	Intravenous (not			Not Reported	
Pemphigus; Pericarditis;					otherwise specified)				
Rash; Rheumatoid	Remicade			S	Unknown			Not Reported	
Arthritis; Rheumatoid									
Factor Positive; Swelling;	Orencia			S	Intravenous (not			Not Reported	
Synovitis; Systemic Lupus					otherwise specified)				
Erythematousus; Treatment	Orencia			S	Subcutaneous			Not Reported	
Failure; Wound									
	Cimzia			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Arava			S	Oral			Not Reported	
	Arava			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported	
	Sulfate]								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Cortisone	S	Unknown	Not Reported
Apo-Folic Acid	S	Unknown	Not Reported
Apo-Folic Acid	S	Oral	Not Reported
Apo-Folic Acid	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Topicort	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Stelara	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Not Reported
Paracetamol	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Topicort Lp	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	15897378	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-002605		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Topicort			S	Subcutaneous			Not Reported
Adverse Drug Reaction;	Diclofenac Sodium			S	Unknown			Bausch And Lomb
Adverse Event; Alopecia;	Cortisone Acetate			S	Oral			Not Reported
Anti-Cyclic Citrullinated	Desoximetasone			S	Cutaneous			Not Reported
Peptide Antibody Positive;	Desoximetasone			S	Unknown			Not Reported
Arthropathy; Condition	Desoximetasone			S	Oral			Not Reported
Aggravated;	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
Contraindicated Product	Cortisone Acetate			S	Unknown			Not Reported
Administered; Discomfort;	Actemra			S	Intravenous (not			Not Reported
Drug Ineffective; Drug					otherwise specified)			
Intolerance; Fatigue;								
Glossodynia; Hand								
Deformity; Hepatic								
Enzyme Increased; Hip								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthroplasty; Infusion	Actemra	S	Unknown		Not Reported
Related Reaction; Joint Swelling; Knee	Arava	S	Oral		Not Reported
Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain;	Arava	S	Unknown		Not Reported
Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Sunconjunctival		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Plaquenil	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified) Powder For Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified) Therapy Duration 365 (Unspecified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral Therapy Duration: 365 (Unspecified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Apo Folic	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Stelara	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfathalidine			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	16066887	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1022788		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Off Label Use; Pruritus; Rash Maculo-Papular	Repaglinide			S	Oral	Unk		Not Reported	
	Coversyl /00790702/			S	Oral	Unk		Mylan	
	Coversyl /00790702/			S	Unknown	Unk Unk,Unk		Mylan	
	Plaquenil /00072603/			S	Oral	200 Mg/ Day		Mylan	
	Cortancyl			S	Oral	10-20µg		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	16217782	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190424225		14 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S				Not Reported	
	Remicade			S				Not Reported	
	Acetazolamide			S	Unknown			Not Reported	
	Alendronate Sodium			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S				Not Reported	
	Azathioprine			S				Not Reported	
	Calcium Carbonate			S	Unknown			Not Reported	
	Cyclosporine			S	Unknown			Not Reported	
	Cyclosporine			S				Not Reported	
	Ferric Hydroxide Polymaltose Complex			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Amlodipine	S	Unknown	Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Metformin	S	Unknown	Not Reported
Nutropin	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Protropin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	16693247	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208351		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic	Arava			S	Oral	Unk Unk, Unk		Sanofi
	Plaquenil			S	Oral	400 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Hydroxychloroquine Sulfate			S		400 Mg		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Codeine			S	Unknown	Unk Unk, Unk		Not Reported
	Actemra			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Adalimumab			S	Unknown	Unk Unk, Unk		Not Reported
	Anakinra			S	Unknown	Unk Unk, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Cimzia	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Simponi	S	Subcutaneous	50 Mg, Qm	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Unknown	30 Mg, Qw	Not Reported
	Prednisone	C		35 Mg, Qd	Not Reported
	Xeljanz	C	Unknown	Unk Unk, Unk	Not Reported
	Simponi	C	Subcutaneous	50 Mg	Not Reported
	Adalimumab	C		Unk	Not Reported
	Sulfasalazine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	16693818	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208304		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Iron Abnormal; Condition	Arava			S	Oral	Unk Unk, Unk		Sanofi
Aggravated; Disease Progression; Drug	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
Hypersensitivity; Drug	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
Ineffective; Drug	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported
Intolerance; Off Label Use;	Mycophenolate Mofetil			S	Unknown	Unk Unk, Unk		Not Reported
Psoriatic Arthropathy;	Pregabalin			S	Unknown	Unk Unk, Unk		Not Reported
Rash; Rheumatoid Arthritis; Sciatica;	Sulfasalazine			S	Unknown	Unk Unk, Unk		Not Reported
Sinusitis; Therapeutic Product Effect Incomplete;	Plaquenil			S	Unknown	Unk Unk, Unk		Sanofi
Treatment Failure	Actemra			S		640 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S		640 Mg, Unk	Not Reported
Actemra	S		640 Mg, Qw	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk Unk, Unk	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg For 9.0 Month(S)	Not Reported
Certolizumab Pegol	S	Unknown	200 Mg For 9.0 Month(S)	Not Reported
Ciclosporin	S	Oral	Unk Unk, Unk	Not Reported
Ciclosporin	S	Oral		Not Reported
Ciclosporin	S	Oral		Not Reported
Cimzia	S	Subcutaneous	200 Mg, Single-Use Prefilled Syringe	Not Reported
Cimzia	S	Subcutaneous	200 Mg Qw, Single-Use Prefilled Syringe	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Qw	Not Reported
Enbrel	S	Unknown	50 Mg, Unk For 4 Years	Not Reported
Gold	S	Unknown	Unk Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qw For 4 Years	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	400 Mg, Qw	Not Reported
Imuran [Azathioprine Sodium]	S	Unknown	Unk Unk, Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Qw For 2 Years	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk Unk, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
Simponi	S	Unknown	Unk Unk, Unk	Not Reported
Rituxan	S	Unknown	Unk Unk, Unk	Not Reported
Piroxicam	C			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone			C		Unk Unk, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	16731220	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1095844		16 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Methotrexate			S	Unknown			Barr	
Clear Cell Renal Cell	Methotrexate			S				Barr	
Carcinoma; Complications	Ciclosporin			S	Unknown			Ivax	
Of Bone Marrow	Ciclosporin			S				Ivax	
Transplant; Hair Follicle	Etoposide			S	Unknown			Teva	
Tumour Benign;	Etoposide			S				Teva	
Hepatosplenic T-Cell	Anakinra			S	Subcutaneous			Not Reported	
Lymphoma; Hypotension;	Enbrel			S	Unknown	.7143 Milligram Daily;		Not Reported	
Lymphoproliferative	Enbrel			S	Unknown			Not Reported	
Disorder; Off Label Use;	Infliximab			S	Intravenous (not			Not Reported	
Product Use In					otherwise specified)				
Unapproved Indication;	Infliximab			S				Not Reported	
Product Use Issue;									
Pyrexia; Splenomegaly; T-	Infliximab			S				Not Reported	
Cell Lymphoma;	Tacrolimus			S	Unknown			Not Reported	
Tachycardia;	Thalidomide			S	Oral			Not Reported	
Thrombocytopenia	Etanercept			S	Unknown			Not Reported	
	Etanercept			S				Not Reported	
	Kineret 100mg Per Syringe			S	Subcutaneous			Not Reported	
	Single-Use,Preservative-Free								
	Prefilled Syrin								
	Remicade			S	Intravenous (not	33.3333 Milligram Daily;		Not Reported	
					otherwise specified)				
	Remicade			S				Not Reported	
	Acetazolamide			S	Unknown			Not Reported	
	Alendronate Sodium			S	Unknown			Actavis	
	Amlodipine			S	Unknown			Teva	
	Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azathioprine	S		Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Cyclophosphamide	S	Unknown	Not Reported
Enalapril	S	Unknown	Not Reported
Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Leflunomide	S	Unknown	Barr
Leflunomide	S		Barr
Metformin	S	Unknown	Actavis
Nutropin	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Actavis
Protropin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported
Erelzi 25 Mg Solution For Injection In Prefilled Syringe	S	Subcutaneous	Not Reported
Etoposide	C		Not Reported
Kineret 100mg Per Syringe Single-Use,Preservative-Free Prefilled Syrin	C		Not Reported
Tacrolimus	C		Not Reported
Thalidomide Celgene -50 Mg Capsula Rigida - Celgene Europe Limited	C		Not Reported
Thalomid	C		Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	16805798	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-201908000239			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaemia; Eye	Hydroxychloroquine	S	Unknown	Unk	Concordia
Haemorrhage; Weight Increased	Dupixent	S	Subcutaneous	Unk Loading Dose	Not Reported
	Dupixent	S	Subcutaneous	300 Mg, Qow	Not Reported
	Dupilumab Pre-Filled Syringe	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17027053	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA305395		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Triamcinolone Acetonide			S	Unknown	Unk Unk, Unk		Sanofi
Arthritis; Body Height	Methotrexate			S	Subcutaneous	15 Mg/M2, Qow		Not Reported
Below Normal; Bone	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
Density Decreased; C-	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
Reactive Protein	Prednisone			S	Oral	3 Mg, Bid		Not Reported
Increased; Condition	Prednisone			S	Oral	3 Mg, Bid		Not Reported
Aggravated; Diarrhoea;	Prednisone			S	Oral	5 Mg, Bid		Not Reported
Dizziness; Drug	Prednisone			S		1.3 Unk		Not Reported
Ineffective; Drug	Sulfasalazine			S	Oral	250 Mg, Qd		Not Reported
Intolerance; Human	Actemra			S	Intravenous (not otherwise specified)	280 Mg, Qw		Not Reported
Antichimeric Antibody	Anakinra			S	Subcutaneous	50 Mg, Qw		Not Reported
Positive; Joint Effusion;	Anakinra			S	Subcutaneous	50 Mg, Qd		Not Reported
Joint Injury; Juvenile	Enbrel			S	Subcutaneous	25 Mg, Qow		Not Reported
Idiopathic Arthritis; Mobility	Enbrel			S	Subcutaneous	12.5 Mg, Qw		Not Reported
Decreased; Nausea;	Humira			S	Subcutaneous	Unk, Unk		Not Reported
Obesity; Off Label Use;	Infliximab			S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
Polyarthritis; Psoriasis;	Infliximab			S	Intravenous (not otherwise specified)	3 G, Qw		Not Reported
Red Blood Cell	Orencia			S	Intravenous (not otherwise specified)	250 Mg, Qm		Not Reported
Sedimentation Rate								
Increased; Septic Shock;								
Synovitis; Vomiting								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17033136	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-SA-2019SA308981		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Triamcinolone Acetonide			S		Unk		Sanofi
Antibody Test Positive;	Triamcinolone Acetonide			S				Sanofi
Arthritis; Arthropathy;	Triamcinolone Acetonide			S		Unk		Sanofi
Body Height Below	Triamcinolone Acetonide			S		Unk		Sanofi
Normal; Bone Density	Triamcinolone Acetonide			S		Unk		Sanofi
Decreased; C-Reactive	Triamcinolone Acetonide			S	Intra-articular	Unk		Sanofi
Protein Increased;	Hydroxychloroquine			S	Oral	5 Mg, Qd		Sanofi
Condition Aggravated;	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Sanofi
Diarrhoea; Dizziness;	Hydroxychloroquine			S	Oral	Unk		Sanofi
Drug Ineffective; Drug	Hydroxychloroquine			S	Oral	Unk		Sanofi
Intolerance; Drug Specific	Naproxen			S		Unk		Not Reported
Antibody Present;	Naproxen			S	Oral	3 Mg, Qd		Not Reported
Gastroenteritis Viral;	Naproxen			S	Oral	5 Mg, Qd		Not Reported
Human Anti-Human	Naproxen			S	Unknown	Unk Unk, Unk		Not Reported
Antibody Test; Human	Naproxen			S				Not Reported
Antichimeric Antibody	Prednisone			S	Oral	1.3 Mg, Bid		Not Reported
Positive; Hypocalcaemia;	Prednisone			S	Oral	3 Mg, Bid		Not Reported
Hypokalaemia;	Prednisone			S	Oral	50 Mg, Bid		Not Reported
Hypotension;	Prednisone			S		50 Unk		Not Reported
Immunodeficiency;	Prednisone			S		Unk		Not Reported
Impaired Quality Of Life;	Prednisone			S	Oral	3 Mg, Bid		Not Reported
Joint Destruction; Joint	Prednisone			S	Oral	5 Mg, Bid		Not Reported
Effusion; Joint Injury;	Prednisone			S		1.3 Mg, Bid		Not Reported
Juvenile Idiopathic	Prednisone			S		250 Mg, Qd		Not Reported
Arthritis; Liver Function	Prednisone			S	Oral	15 Mg/M2, Qw		Not Reported
Test Abnormal; Loss Of	Prednisone			S	Oral	Unk Unk, Qw		Not Reported
Consciousness; Loss Of	Prednisone			S	Oral			Not Reported
Personal Independence In	Prednisone			S	Oral			Not Reported
Daily Activities; Mobility	Sulfasalazine			S	Oral			Not Reported
Decreased; Nausea;	Sulfasalazine			S				Not Reported
Obesity; Off Label Use;	Methotrexate			S	Subcutaneous			Not Reported
Pleural Effusion;	Methotrexate			S				Not Reported
Polyarthritis; Prescribed	Methotrexate			S				Not Reported
Underdose; Product Use								Not Reported
Issue; Psoriasis; Pyrexia;								Not Reported
Red Blood Cell								Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sedimentation Rate	Methotrexate	S	Subcutaneous	Unk Unk, Qw	Not Reported
Increased; Rheumatoid	Methotrexate	S		Unk	Not Reported
Arthritis; Septic Shock;	Methotrexate	S	Subcutaneous	Unk	Not Reported
Synovitis; Therapeutic	Methotrexate	S	Subcutaneous	15 Mg, Qow	Not Reported
Product Effect Decreased;	Immune Globulin	S	Intravenous (not	Unk	Not Reported
Therapy Non-Responder;	(Immunoglobulins Nos)		otherwise specified)		
Vomiting; Wheelchair User	Immune Globulin	S	Intravenous (not	70 G	Not Reported
	(Immunoglobulins Nos)		otherwise specified)		
	Immune Globulin	S	Intravenous (not	70 G	Not Reported
	(Immunoglobulins Nos)		otherwise specified)		
	Immune Globulin	S	Intravenous (not	70 G	Not Reported
	(Immunoglobulins Nos)		otherwise specified)		
	Infliximab	S	Intravenous (not	3 Mg	Not Reported
			otherwise specified)		
	Infliximab	S	Intravenous (not	Unk	Not Reported
			otherwise specified)		
	Infliximab	S	Intravenous (not	3 Mg/Kg, Q6w	Not Reported
			otherwise specified)		
	Infliximab	S	Intravenous (not	5 Mg	Not Reported
			otherwise specified)		
	Infliximab	S		Unk Unk, Qw	Not Reported
	Infliximab	S	Intravenous (not	Unk, Q6w	Not Reported
			otherwise specified)		
	Kineret	S	Subcutaneous	50 Mg, Qd	Not Reported
	Kineret	S	Subcutaneous	Unk Unk, Qd	Not Reported
	Orencia	S	Intravenous (not	250 Mg, Qm	Not Reported
			otherwise specified)		
	Orencia	S	Intravenous (not	250 Mg, Qm	Not Reported
			otherwise specified)		
	Orencia	S	Intravenous (not	Unk Unk, Qm	Not Reported
			otherwise specified)		
	Orencia	S	Intravenous drip	250 Mg, Q2m	Not Reported
	Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Orencia	S	Respiratory (inhalation)	250 Mg, Qm	Not Reported
Orencia	S	Intravenous (not otherwise specified)	250 Unk	Not Reported
Orencia	S		Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S		Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qw	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qod	Not Reported
Actemra	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Etanercept	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Etanercept	S	Subcutaneous	25 Mg, Biw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg, Qow	Not Reported
Enbrel	S	Subcutaneous	12.5 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	25 Mg	Not Reported
Abatacept	S	Intravenous drip	250 Mg, Qm	Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S		Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anakinra	S	Subcutaneous	50 Mg, Qw	Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
Anakinra	S		50 Unk	Not Reported
Anakinra	S	Subcutaneous	Unk	Not Reported
Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
Anakinra	S		Unk	Not Reported
Orencia	S			Not Reported
Orencia	S	Intravenous drip	250 Mg, Qm	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qow	Not Reported
Folic Acid	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17069951	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-201911001908			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthralgia; Bacterial Infection; Contusion; Cystitis; Fatigue; Feeling Abnormal; Hemiparesis; Hysterectomy; Insomnia; Pain; Pain In Extremity; Ph Body Fluid Abnormal; Pyrexia; Tremor; Vaginal Haemorrhage; Vulvovaginal Mycotic Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Teriflunomide			S	Oral	14 Mg, Qd (Coated Tablet)		Not Reported
	Teriflunomide			S	Oral	14 Mg, Qd		Not Reported
	Fludrocortisone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17419878	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543667		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17653955	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-017958		75 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Lopinavir;Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	20 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17716072	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-020311		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged; Long Qt Syndrome; Sudden Death	Azithromycin	S	Oral	500 Milligram, Once A Day	Aurobindo
	Salbutamol	S	Respiratory (inhalation)	0.1 Milligram, Four Times/Day	Not Reported
	Dolquine	S	Oral	400 Milligram, Two Times A Day	Not Reported
	Propofol	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Metoclopramide	S	Intravenous (not otherwise specified)	10 Milligram, 3 Times A Day	Not Reported
	Ipratropium Bromide	C	Respiratory (inhalation)	20 Microgram, Four Times/Day	Not Reported
	Enoxaparin Sodium	C	Subcutaneous	Unk	Not Reported
	Cefotaxime	C	Intravenous drip	4 Gram, Two Times A Day	Not Reported
	Midazolam	C	Intravenous drip	100 Milligram, Once A Day	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	600 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17721946	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227338		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported
	Dolquine			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine			S		Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17724166	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166893		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731644	EXPEDITED (15-DAY)		HO, LT, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245540		36 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased	Tacrolimus			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Sun	
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported	
	Cobicistat/Darunavir			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731661	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004004082			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Dizziness; Ear Pain; Eye Injury; Headache; Herpes Virus Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731724	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA-202004004144			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Respiratory Distress Syndrome; Hepatocellular Injury; Off Label Use	Hydroxychloroquine	S	Oral	400 Mg, Qd, Film-Coated Tablet	Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731781	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589712		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
Xeljanz			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731830	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588725			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588961		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

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Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732413	EXPEDITED (15-DAY)	HO		CA-ROCHE-2587291		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abscess; Adrenal Insufficiency; Alanine Aminotransferase Increased; Ascites; Asthenia; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Blood Potassium Decreased; Blood Pressure Diastolic Abnormal; Blood Pressure Increased; Congestive Hepatopathy; Depression; Diverticulitis; Endometrial Disorder; Enterococcus Test Positive; Fibrosis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Furosemide			S	Unknown			Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rosuvastatin Calcium			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gamma-Glutamyltransferase Increased; Gastrointestinal Disorder; Generalised Oedema; Heart Rate Increased; Herpes Zoster; Hypersensitivity; Hypoglycaemia; Hypotension; Increased Appetite; Influenza; Infusion Related Reaction; Injection Site Extravasation; Intensive Care Unit Acquired Weakness; Intervertebral Disc Protrusion; Joint Effusion; Joint Swelling; Micturition Disorder; Myelopathy; Myopathy; Nasopharyngitis; Nausea; Nerve Compression; Neuropathy Peripheral; Neutropenia; Osteoarthritis; Pancytopenia; Peripheral Sensorimotor Neuropathy; Peritonitis; Pneumonia; Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Acetaminophen Actonel Apo Amlo Apo-K Diphenhydramine Hydrochloride Epoetin Alfa Escitalopram Hydrochlorothiazide Hydroxychloroquine Insulin Lispro Januvia Kcl Metformin Methylprednisolone Metoprolol Pantoloc [Pantoprazole] Pantoprazole Risedronate Slow-K Tylenol Ventolin [Salbutamol]	C C C C C C C C C C C C C C C C C C C C C C	Unknown Unknown	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589459		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Carpal Tunnel	Actemra			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Condition	Apo-Leflunomide	S	Unknown		Not Reported
Aggravated;	Enbrel	S	Unknown		Not Reported
Contraindicated Product	Hydroxychloroquine	S	Unknown		Not Reported
Administered; Drug	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Ineffective; Drug	Leflunomide	S	Unknown		Not Reported
Intolerance; Gait	Methotrexate	S	Unknown	Duration 4 Month	Not Reported
Disturbance; Hip Fracture;	Methotrexate	S	Unknown	Duration 4 Month	Not Reported
Intervertebral Disc	Orencia	S	Unknown	Duration 4 Month	Not Reported
Disorder; Knee	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Duration 4 Month	Not Reported
Arthroplasty; Mobility	Prednisone	S	Unknown	Duration 4 Month	Not Reported
Decreased;	Remicade	S	Unknown	Duration 4 Month	Not Reported
Musculoskeletal	Remicade	S	Intravenous (not otherwise specified)	Duration 4 Month	Not Reported
Discomfort; Nausea; Pain;	Simponi	S	Subcutaneous	Duration 4 Month	Not Reported
Rheumatoid Arthritis;	Xeljanz	S	Oral	Duration 4 Month	Not Reported
Stress Fracture; Vomiting;					
Wrist Deformity					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732474	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202004003662			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732521	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202004002893			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Effective For	Hydroxychloroquine			S		Unk		Concordia
Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732668	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2020168162		38 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycin			S		500 Mg, Daily		Pfizer	
	Azithromycin			S				Pfizer	
	Dexmedetomidine Hydrochloride			S		Unk		Pfizer	
	Dexmedetomidine Hydrochloride			S				Pfizer	
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Favipiravir			C				Not Reported	
	Methylprednisolone			C		1 Mg/Kg		Not Reported	
	Ceftriaxone			C		2 G		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588738			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Topical			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587807		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Product Use Issue; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Ciclosporin			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733312	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229092		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; C-Reactive Protein Abnormal; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Jaw Fracture; Joint Swelling; Musculoskeletal Pain; Neck Pain; Overlap Syndrome; Pain In Extremity; Pain In Jaw; Red Blood Cell Sedimentation Rate Abnormal; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Ciclosporin			S	Unknown			Ivax	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Azathioprine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733315	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229034		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chest Pain; Drug Intolerance; Dyspnoea; Elbow Deformity; Fatigue; Joint	Azathioprine			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Ivax	
	Methotrexate			S	Unknown			Barr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling; Musculoskeletal Pain; Neck Pain; Pain In Jaw; Sle Arthritis; Toxicity To Various Agents; Weight Decreased	Mycophenolate Mofetil	S	Unknown	Teva
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733337	EXPEDITED (15-DAY)		HO	ES-BAYER-2020-066313		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diarrhoea; Hepatitis; Hypokalaemia	Betaferon			S	Subcutaneous	0.25 Mg		Bayer	
	Betaferon			S				Bayer	
	Dolquine			S	Oral	400 Mg Dia		Not Reported	
	Kaletra			S	Oral	2 Df, Bid		Not Reported	
	Kaletra			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733717	EXPEDITED (15-DAY)		OT	US-ABBVIE-20K-163-3387130-00			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Systemic Lupus Erythematosus	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733894	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588759			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not			Not Reported	

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Device Implantation

Arava	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734070	NON-EXPEDITED		HO, OT	PL-AMGEN-POLSP2020070504		35 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis Of Pregnancy; Erythema Nodosum; Maternal Exposure During Pregnancy; Normal Newborn; Ultrasound Scan Abnormal	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	15 Milligram, Qwk		Not Reported
	Encorton [Prednisone Acetate]			S	Unknown	15 Milligram, Qd		Not Reported
	Encorton [Prednisone Acetate]			S	Unknown	10 Milligram, Qd		Not Reported
	Plaquenil S			S	Unknown	20 Milligram, Qd		Not Reported
	Erelzi [Etanercept]			S	Intravenous (not otherwise specified)	50 Milligram		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Erelzi [Etanercept]			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Benepali			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Metex [Methotrexate Sodium]			C	Subcutaneous	Unk (The Last Injection In Jan-2019))		Not Reported
	Folic Acid			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734176	EXPEDITED (15-DAY)		DE, OT	CH-SA-2020SA109443		72 YR	Male	CHE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemolytic Anaemia; Off Label Use; Thrombocytopenia; Thrombotic Microangiopathy	Plaquenil			S	Oral	800 Mg/Day From 22 To 23 Mar 2020, 400 Mg/Day From 24 To 26 Mar 2020, 600 Mg/Day From 26 To 30 Mar 2		Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S	Oral	200 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg		Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S	Intravenous drip	3.6 G, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Fentanyl			S	Transdermal	25 Ug/H		Not Reported
	Piperacillin + Tazobactam			C	Intravenous (not otherwise specified)	13.5 G		Not Reported
	Paracetamol			C		500 Mg, Qid		Not Reported
	Paracetamol			C		500 Mg		Not Reported
	Humulus Lupulus Extract;Valeriana Officinalis Extract			C				Not Reported
	Macrogol			C		Unk Unk, Qd		Not Reported
	Metoclopramide			C		10 Mg, Tid		Not Reported
	Relaxane			C		Unk Unk, Tid		Not Reported
	Supradyn [Minerals Nos;Vitamins Nos]			C		Unk Unk, Qd		Not Reported
	Redormin [Remifentanil Hydrochloride]			C		500 Mg, Qd		Not Reported
	Dexamethasone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734253	EXPEDITED (15-DAY)		OT	CA-SA-2020SA112718		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Desoximetasone			S	Oral	Unk		Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alopecia; Contraindicated	Cortisone Acetate	S		Unk	Not Reported
Product Administered;	Alendronate Sodium	S		Unk	Not Reported
Drug Ineffective;	Arava	S		Unk	Sanofi
Hypersensitivity; Maternal	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
Exposure During	Folic Acid	S	Unknown	5 Mg	Not Reported
Pregnancy; Pain;	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
Pemphigus; Pericarditis;	Methotrexate	S		20 Mg, Qd	Not Reported
Product Use Issue;	Methotrexate	S	Oral	25 Mg	Not Reported
Rheumatoid Arthritis;	Prednisone	S	Unknown	Unk	Not Reported
Systemic Lupus	Plaquenil	S	Unknown	400 Mg	Sanofi
Erythematosis; Treatment	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Sanofi
Failure	Sulfasalazine	S	Oral	1000 Mg	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride And	S	Unknown	Unk	Not Reported
	Pseudoephedrine Hydrochloride	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Golimumab	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Diclofenac	C		Unk	Not Reported
	Salazopyrin	C		Unk	Not Reported

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734523	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2020171826		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Zithromax			S	Other	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734550	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020171235		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Loss Of Consciousness; Malaise; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734833	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589482			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue;	Actemra			S	Unknown			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine Hydrochloride			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Systemic Lupus Erythematosus; Wound	Zyrtec-D	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Topicorten	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Desoximetasone	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Desoximetasone	S	Unknown	Not Reported
Folic Acid	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734929	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1042716			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Nightmare;	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
Product Use In	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan
Unapproved Indication;								
Psychomotor Hyperactivity								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17735719	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-012941		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alopecia;	Desoximetasone			S	Unknown			Not Reported
Anti-Cyclic Citrullinated	Desoximetasone			S	Unknown			Not Reported
Peptide Antibody Positive;	Desoximetasone			S	Oral			Not Reported
Arthropathy; Condition	Cortisone Acetate			S	Oral			Not Reported
Aggravated; Discomfort;	Cortisone			S	Oral			Not Reported
Drug Ineffective; Drug	Diclofenac Sodium			S	Unknown			Not Reported
Intolerance; Duodenal	Topicort			S	Subcutaneous			Not Reported
Ulcer Perforation; Fatigue;	Topicort			S	Unknown			Not Reported
Glossodynia; Hand	Topicort			S	Oral			Not Reported
Deformity; Hepatic	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Enzyme Increased;	Actemra			S	Subcutaneous			Not Reported
Hypersensitivity; Infusion	Apo Prednison			S	Unknown			Not Reported
Related Reaction;	Arava			S	Oral			Not Reported
Intentional Product Use	Arava			S	Oral			Not Reported
Issue; Joint Swelling; Live								
Birth; Maternal Exposure								
During Pregnancy; Off								
Label Use; Pain;								
Pemphigus; Pericarditis;								
Rash; Rheumatoid								
Arthritis; Rheumatoid								
Factor Positive; Swelling;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride, Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Oral		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Leflunomide Sandoz	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfathalidine	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Acetaminophen	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17735914	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-02			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Otezla			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pantoprazole	S	Oral	Tablet (Delayed Release)	Not Reported
Pantoprazole Magnesium	S	Unknown		Not Reported
Synthroid	S	Unknown		Not Reported
Diltiazem Hydrochloride	C	Oral		Not Reported
Fluticasone Propionate	C	Respiratory (inhalation)		Not Reported
Mar-Pantoprazole	C	Unknown		Not Reported
Mometasone Furoate	C	Unknown		Not Reported
Premarin	C	Unknown		Not Reported
Salbutamol Sulfate	C	Respiratory (inhalation)		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736149	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020176534			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rectal Cancer	Xeljanz Xr			S		11 Mg, 1x/Day (11mg Qd)		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736216	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012554			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Cortisone Acetate			S	Unknown			Not Reported	
Alopecia; Anti-Cyclic	Cortisone			S	Oral			Not Reported	
Citrullinated Peptide	Cortisone			S	Unknown			Not Reported	
Antibody Positive;	Topicort			S	Unknown			Not Reported	
Condition Aggravated;	Topicort			S	Subcutaneous			Not Reported	
Discomfort; Drug	Diclofenac Sodium			S	Unknown			Not Reported	
Ineffective; Drug									
Intolerance; Fatigue;									
Glossodynia; Hand									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deformity; Hepatic	Acetaminophen	S	Unknown	Not Reported
Enzyme Increased; Hip	Actemra	S	Unknown	Not Reported
Arthroplasty;	Apo-Prednisone	S	Unknown	Not Reported
Hypersensitivity; Infusion	Arava	S	Oral	Not Reported
Related Reaction; Joint	Cetirizine Hydrochloride	S	Unknown	Not Reported
Swelling; Knee	Cetirizine Hydrochloride	S	Unknown	Not Reported
Arthroplasty; Maternal	Cetirizine	S	Unknown	Not Reported
Exposure During	Hydrochloride/Pseudoephedrine			
Pregnancy; Pain;	Hydrochloride			
Pemphigus; Pericarditis;	Cimzia	S	Subcutaneous	Not Reported
Rash; Rheumatoid	Desoximetasone	S	Oral	Not Reported
Arthritis; Rheumatoid	Enbrel	S	Subcutaneous	Not Reported
Factor Positive; Swelling;	Folic Acid	S	Unknown	Not Reported
Synovitis; Systemic Lupus	Folic Acid	S	Oral	Not Reported
Erythematosis; Treatment	Fosamax	S	Unknown	Not Reported
Failure; Wound	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Topicort	S	Subcutaneous	Not Reported
Atasol	C		Not Reported
Salazopyrina	C		Not Reported
Tofacitinib Citrate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736256	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-02			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Influenza Like Illness; Musculoskeletal Stiffness; Pain; Psoriatic Arthropathy; Tenosynovitis; Treatment Failure	Mobicox			S	Oral			Boehringer Ingelheim
	Cosentyx			S	Oral			Not Reported
	Diclofenac			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leucovorin Calcium			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Otezla	S	Unknown	Not Reported
Pantoprazole	S	Oral	Not Reported
Pantoprazole Magnesium	S	Unknown	Not Reported
Synthroid	S	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported
Salbutamol Sulfate	C	Respiratory (inhalation)	Not Reported
Mometasone Furoate	C	Unknown	Not Reported
Mar-Pantoprazole	C	Unknown	Form Of Admin: Tablet (Delayed-Release) Not Reported
Fluticasone Propionate	C	Respiratory (inhalation)	Not Reported
Diltiazem Hydrochloride	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736716	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2020-021403		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day(Dia)		Aurobindo	
	Azithromycin			S				Aurobindo	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day(Dia)		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported	
	Tocilizumab			S				Not Reported	
	Ceftriaxone			S	Intravenous (not	2 Gram, Once A Day(Dia)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736737	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-093087		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Risedronate Tablet			S	Unknown	35 Milligram, Every Week		Aurobindo
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Once A Day		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	20 Milligram, Once A Day		Not Reported
	Leflunomide			S	Unknown	1 Dosage Form		Not Reported
	Actonel			S	Unknown	35 Milligram, Every Week		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	17.5 Milligram		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	300 Milligram, Once A Day		Not Reported
	Hydroxychloroquine			C	Unknown	300 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736746	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR- APL-2020-021570		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxona			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dolquine	S	Oral	200 Milligram, Two Times A Day	Not Reported
Kaletra	S	Oral	2 Dosage Form, Two Times A Day	Not Reported
Metilprednisolona	S	Intravenous (not otherwise specified)	250 Milligram, Once A Day	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	560 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	15369646	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181868		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Oedema Peripheral; Pyrexia	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	16139048	EXPEDITED (15-DAY)		OT	DE-ACCORD-117446		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Methotrexate			S	Subcutaneous	20 Mg, Tablet Oral		Accord
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Mg, Powder For Solution Intravenous		Not Reported

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Leflunomide	S		Film-Coated Tablet	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Neoral	S	Subcutaneous		Not Reported
Neoral	S	Oral		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Apo-Leflunomide	S	Oral	Also Received Additionally, Film Coated Tablet	Not Reported
Ciclosporin	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Subcutaneous	Also Received Oral Tablet	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Apo-Hydroxyquine	S	Oral	Unk, Also Received Subcutaneous Apo- Hydroxyquine Thrice	Not Reported
Rituxan	S	Unknown	Solution Intravenous	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736773	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR- APL-2020-021363		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Kaletra			S	Oral	2 Dosage Form (2u/2 H)		Not Reported	
	Kaletra			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736776	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019740		77 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Once A Day		Not Reported	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736804	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020847		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	800 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736808	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020857			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736838	EXPEDITED (15-DAY)		HO	ES-HETERO-HET2020ES00483		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg, Qd		Hetero	
	Dolquine			S	Oral	400 Mg, Qd		Not Reported	
	Kaletra			S	Oral	12 Hours Bid (200/50mg)		Not Reported	

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Kaletra			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587376		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Piroxicam			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736873	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-020465		82 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	

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Prolonged; Off Label Use	Haloperidol	S	Oral	5 Gtt Drops, Once A Day	Not Reported
	Plaquenil	S	Oral	600 Milligram, Once A Day	Not Reported
	Teicoplanin	S	Intravenous (not otherwise specified)	400 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736886	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1228537		55 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycine Anhydre			S	Oral	250 Mg		Not Reported
	Plaquenil			S	Oral	600 Mg		Not Reported
	Rocephine			S	Oral	2 G		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17737066	EXPEDITED (15-DAY)		CA, DE, DS, OT	DE-PBT-000161			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Death; Foetal Exposure During Pregnancy; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental	From Gestational Week 0-14		Panacea Biotec
	Tacrolimus			S	Transplacental			Panacea Biotec
	Heparin			S	Transplacental			Not Reported
	Prednisolone			S	Transplacental	From Gestational Week 0-14		Not Reported
	Prednisolone			S	Unknown			Not Reported
	Toraseamide			S	Transplacental	From Gestational Week 0-14		Not Reported
	Toraseamide			S	Transplacental			Not Reported

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Hydroxychloroquine Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental		Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Simvastatin	S	Transplacental	From Gestational Week 0-14	Not Reported
Simvastatin	S	Transplacental		Not Reported
Clexane	S	Transplacental	From Gestational Week 0-14, 200 Mg/D (2x100)	Not Reported
Salbutamol Sulfate	S	Transplacental	From Gestational Week 0-14	Not Reported
Salbutamol Sulfate	S	Transplacental		Not Reported
Acetylsalicylic Acid	S	Transplacental	From Gestational Week 0-14	Not Reported
Acetylsalicylic Acid	S	Transplacental		Not Reported
Rituximab	S	Transplacental	Unk, Last Time In December 2011: Pre Or Periconceptional	Not Reported
Xarelto	S	Transplacental	From Gestational Week 0-5	Not Reported
Xarelto	S	Transplacental		Not Reported
Pantoprazole	S	Transplacental	40 [Mg/D]; 0-13.6 Gestational Week	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Pantoprazole	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental	From Gestational Week 0-14	Not Reported
Ezetimibe	S	Transplacental		Not Reported
Nicotine	S	Transplacental	From Gestational Week 0-14	Not Reported
Nicotine	S	Transplacental		Not Reported

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Ramipril	S	Transplacental	20 Mg, Qd From Gestational Week 0-113+6	Not Reported
Ramipril	S	Transplacental	Maternal Dose 20 Mg, Unk	Not Reported
Aliskiren	S	Transplacental	300 [Mg/D]; 0-4.6 Gestational Week	Not Reported
Aliskiren	S	Transplacental		Not Reported
Aliskiren	S	Transplacental		Not Reported
Metamizole Sodium	S	Transplacental	From Gestational Week 0-14	Not Reported
Metamizole Sodium	S	Transplacental		Not Reported
Misoprostol	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Novaminsulfon	S	Transplacental	Unk; Trimester: First; Probably Only In Hospital In Week 5	Not Reported
Cyclophosphamide	C	Transplacental	3000 [Mg Cumulative]; Preconceptional	Not Reported
Mifepristone	C	Transplacental	Unk; 13.6 Gestational Week	Not Reported
Enoxaparin Sodium	S	Transplacental	(From Gestational Week 0-14)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17737105	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230648			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug Intolerance; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Ciclosporin			S	Unknown			Ivax
	Ciclosporin			S	Unknown			Ivax
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous	25 Mg, 1 Every 1 Week		Barr
	Actemra			S	Subcutaneous			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported

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Azathioprine	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral 400 Milligram Daily;	Not Reported
Kevzara	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Magnesium	C		Not Reported
Metformin	C	Unknown	Not Reported
Xeljanz	C	Oral 10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17737108	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1229118		61 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deep Vein Thrombosis;	Hidroxicloroquina (2143a)			S	Oral			Teva	
Drug Interaction;	Hidroxicloroquina (2143a)			S				Teva	
Hypofibrinogenaemia;	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)			Not Reported	
Melaena; Sepsis	Tocilizumab (8289a)			S				Not Reported	
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported	
	Dexametasona (722a)			C	Intravenous (not otherwise specified)	20mg/24h Los Primeros 5 Dias, Posteriormente 10 Mg/24h Durante 5 Dias Más.		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17737152	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2020-DE-1229088		82 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Acute Hepatic Failure; Off Label Use	Hydroxychloroquine	S	Oral	400 Milligram Daily; 1-0-1	Teva
	Hydroxychloroquine	S			
	Azithromycin	C			
	Azithromycin	C			
	Piperacillin/Tazobactam	C			
	Piperacillin/Tazobactam	C			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17737198	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1229150		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Mg		Teva
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	800mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	14308678	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050900		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Etanercept			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

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Remicade	S	otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S		Unk	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Weekly (Qw)	Not Reported
Methotrexate	C	Oral	25 Mg, Weekly (Qw)	Not Reported
Plaquenil	C		200 Mg, 2x/Day (Bid)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737230	EXPEDITED (15-DAY)		HO	CA-ROCHE-2590268		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Folic Acid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737254	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590321		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Actemra Anakinra Apo-Leflunomide Enbrel Humira Hydroxychloroquine Hydroxychloroquine Sulfate Leflunomide Methotrexate Orencia	S S S S S S S S S S	Intravenous (not otherwise specified) Subcutaneous Unknown Subcutaneous Subcutaneous Unknown Unknown Unknown Unknown Intravenous (not otherwise specified)	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737289	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589205			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Drug Ineffective; Drug Intolerance	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737294	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017839		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Solution		Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sarilumab			S				Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S				Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S	Oral	5milligram, 2 Every 1 Days		Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Folic Acid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737316	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020161825		40 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Product Use In
Unapproved Indication

Sulfate]

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	12182291	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1723643		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Sleep Disorder; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous	Therapy Duration: 2.0 Month(S)		Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Urethral			Not Reported
	Methotrexate Sodium			S	Oral	(2.5 Mg- 8 Tablets Orally Once Weekly)		Not Reported
	Methotrexate Sodium			S	Unknown	Solution For Injection		Not Reported
	Methotrexate Sodium			S	Oral	Therapy Duration: 24.0 Year(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	Therapy Duration 24.0 Years		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown	Solution For Injection		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported
Cymbalta			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	12891950	EXPEDITED (15-DAY)		HO, LT, OT	CA-AOPHARMA INC-2016AP013468			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Hydroxychloroquine			S				Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Leflunomide			S	Oral	Unk		Apotex	
	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Apo-Leflunomide			S				Apotex	
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S				Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S				Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S				Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Ilaris			S	Subcutaneous	Unk		Not Reported	
	Ilaris			S	Unknown	Unk Unk, Unknown		Not Reported	
	Ilaris			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S			Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13054285	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015721			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Oral	10 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	200 Mg, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Actemra	C	Subcutaneous	Unk	Not Reported
Enbrel	C	Subcutaneous	Unk	Not Reported
Humira	C	Unknown	40 Mg, Unk	Not Reported
Methotrexate	C	Unknown	Unk	Not Reported
Orencia	C	Unknown	Unk	Not Reported
Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown		Not Reported
Simponi	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13058845	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015768		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk, Qd		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Unk	Not Reported
Abatacept	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Oral	22.5 Mg, Q.Wk.	Not Reported
Methotrexate Sodium	S			Not Reported
Methotrexate	S	Oral	22.5 Mg, Q.Wk.	Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Parenteral	25 Mg, Q.Wk.	Not Reported
Methotrexate	S	Parenteral	25 Mg, 1 Every 4 Weeks	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Adalimumab	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Subcutaneous	Unk	Not Reported
Ciclosporin	C	Unknown	Unk	Not Reported
Azathioprine	C	Unknown	Unk Unk, Qd	Not Reported
Penicillamine	C	Unknown	Unk	Not Reported
Minocycline	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	6 Mg, Qd	Not Reported
Tocilizumab	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	6 Mg, Bid	Not Reported
Actemra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
D-Penicillamine	C	Unknown	Unk	Not Reported
Phenylbutazone	C	Unknown	Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13059209	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015767			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown			Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072603/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13251533	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006675		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness;	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	Unk (Therapy Duration:		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress				129 Unit Unspecified)	
	Enbrel	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	125 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Mefenamic Acid	C	Unknown		Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Dequalinium Chloride	C	Unknown	Unk	Not Reported
	Advil /00044201/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13939347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017491		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex	
	Leflunomide			S	Oral	20 Mg, Qd		Apotex	

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Apo-Leflunomide	S	Oral	20 Mg, Qd	Apotex
Actemra	S	Unknown		Not Reported
Lyrica	S	Oral	150 Mg, Bid	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Q.Wk.	Not Reported
Tylenol /00020001/	C	Unknown	Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13946397	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017455		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown	Unk		Not Reported
	Apo-Azathioprine			S	Unknown	Unk		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Etanercept			S	Subcutaneous	25 Mg, B.I.Wk.		Not Reported
	Gold			S	Intramuscular	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	13976657	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP018044		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Leflunomide			S	Oral	20 Mg, 1 Every 2 Week		Apotex	
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex	
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported	
	Anakinra			S	Subcutaneous	100 Mg, Qd		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous	40 Mg, 1 Every 2 Weeks		Not Reported	
	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported	
	Methotrexate			S	Oral	12.5 Mg, Qd		Not Reported	
	Methotrexate			S	Subcutaneous	12.5 Mg, Qd		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, 1 Every 4 Weeks		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	500 Mg, Q.M.T.		Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	14235971	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021661		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome;	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	

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Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Enbrel	S	Subcutaneous	1 Df, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Mefenamic Acid	C	Unknown	Unk	Not Reported
	Advil /00044201/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	14747260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2105393		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Pain; Sciatica; Treatment Failure	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Caffeine;Codeine;Paracetamol	S	Unknown	Not Reported
	Tylenol No.2	S	Unknown	Not Reported
	Dorzolamide	S	Ophthalmic	Not Reported
	Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
	Dorzolamide	S	Unknown	Not Reported
	Hydrochloride/Timolol Maleate	S	Unknown	Not Reported
	Dorzolamide	S	Unknown	Not Reported
	Hydrochloride/Timolol Maleate	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Levothyroxine	S	Unknown	Not Reported
	Levothyroxine	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Cosopt	S	Unknown	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Codeine Phosphate	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Methylprednisolone	C		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Tylenol	C		Not Reported
	Acetaminophen	C		Not Reported

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	14815456	EXPEDITED (15-DAY)		OT	CA-ROCHE-2111505		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Actemra			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	15268961	EXPEDITED (15-DAY)		HO	CA-ROCHE-2166736		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Naproxen			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	15330290	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019415			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Unk		Not Reported
	Cimzia			C	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	15337341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP019544		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Obstructive Airways Disorder; Platelet Count Decreased; Pneumonitis; Pulmonary Mass; Restrictive Pulmonary Disease	Apo-Leflunomide			S	Oral	Unk		Apotex
	Leflunomide			S	Oral	Unk		Apotex
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Lipitor			S	Unknown	40 Mg, Qd		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

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Plaquenil /00072602/	S	Oral	300 Mg, Qd	Not Reported
Spiriva	S	Unknown	2.5 Mg, Bid	Not Reported
Zenhale	S	Unknown	200 Mg, Bid	Not Reported
Zenhale	S	Unknown	400 Mg, Bid	Not Reported
Zenhale	S	Unknown	200 Mg, Qd	Not Reported
Tiotropium Bromide Monohydrate	S	Unknown	2.50 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	15342993	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176790		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported

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Codeine	C	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	15389857	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-082887		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Confusional State; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill- Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Abatacept			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Abatacept			S	Unknown	Unk		Bristol Myers Squibb
	Acetaminophen			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram, Q4wk, 84 Days		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Q4wk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram 4 Every 1 Weeks		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Milligram, Qmo		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Milligram		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	725 Milligram		Not Reported
	Chlorhexidine			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported

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Enbrel	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Oxycodone Terephthalate	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Chlorhexidine Gluconate	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
Oxycodone And Acetaminophen	S	Unknown	Unk	Not Reported
Oxycodone	S	Unknown	Unk	Not Reported
Oxycodone Actavis	S	Unknown	Unk	Not Reported
Periogard	S	Buccal	Unk	Not Reported
Apo Acetaminophen	S	Unknown	Unk	Not Reported
Arava	C	Oral	20 Milligram, Qd	Not Reported
Arava	C	Unknown	Unk	Not Reported
Desogestrel And Ethinyl Estradiol	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Pantoprazole Sodium	C	Unknown		Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Prednisone	C	Oral	7.5 Milligram	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported

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Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	400 Milligram, Qd	Not Reported
Tylenol With Codeine	C	Unknown	Unk	Not Reported
Paracetamol Codeine	C	Unknown	Unk	Not Reported
Cetirizine	C	Unknown	Unk	Not Reported
Plaquenil S	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	16003920	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-TEVA-2019-CA-1017774		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Methotrexate			S	Unknown			Barr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein	Methotrexate			S	Unknown			Barr
Increased;	Methotrexate			S	Intra-arterial			Barr
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Methotrexate Sodium			S	Unknown			Barr
Drug Hypersensitivity;	Leflunomide			S	Unknown			Barr
Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Intentional Product Use Issue;	Leflunomide			S	Oral			Barr
Interstitial Lung Disease; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary	Minocycline			S	Unknown			Actavis
	Minocycline Hydrochloride			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Oxycodone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported

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Thrombosis; Red Blood Cell Sedimentation Rate	Arava	S	Unknown		Not Reported
Increased; Renal Failure; Rheumatoid Arthritis;	Enbrel	S	Subcutaneous		Not Reported
Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S			Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous		Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)		Not Reported
	Ilaris Single-Use Vial	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not		Not Reported

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			otherwise specified)	
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Gold	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Marijuana	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Rituximab	S			Not Reported
Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral		Not Reported
Oxyquinoline Sulfate	S	Unknown		Not Reported
Oxyquinoline Sulfate	S			Not Reported
Rituximab/Urelumab	C	Unknown		Not Reported
Kineret	C	Unknown		Not Reported
Lyrica	C	Oral		Not Reported
Lyrica	C			Not Reported
Prednisone	C	Unknown	7 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	16082874	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1022849		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Methotrexate			S	Unknown			Barr
Abnormal; Condition	Methotrexate			S	Unknown			Barr
Aggravated;	Acetaminophen			S	Unknown			Not Reported

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Contraindicated Product	Acetaminophen	S	Unknown		Not Reported
Administered; Drug	Doxycycline Hyclate	S	Unknown	200 Milligram Daily;	Actavis
Hypersensitivity; Drug	Leflunomide	S	Unknown	200 Milligram Daily;	Barr
Ineffective; Drug	Leflunomide	S	Oral	20 Milligram Daily;	Barr
Intolerance; Fatigue; Gait Disturbance;	Actemra	S	Subcutaneous		Not Reported
Hospitalisation; Infection; Intentional Product	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Misuse; Joint Swelling; Loss Of Personal Independence In Daily	Actemra	S	Unknown		Not Reported
Activities; Malaise;	Arava	S	Unknown	20 Milligram Daily;	Not Reported
Nephrolithiasis; Off Label Use; Pain; Pain In	Arava	S	Oral	20 Milligram Daily;	Not Reported
Extremity; Peripheral Swelling; Pneumonia;	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
Rash; Red Blood Cell Sedimentation Rate	Humira	S	Subcutaneous		Not Reported
Increased; Rheumatoid Arthritis; Somnolence;	Orencia	S	Unknown		Not Reported
Therapeutic Product Effect Incomplete; Visual Impairment	Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Apo-Acetaminophen Tab 325mg	S	Unknown		Not Reported
	Apo-Acetaminophen Tab 325mg	S			Not Reported
	Tylenol	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Acetaminophen	S	Unknown		Not Reported

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/Diphenhydramine Hydrochloride	S	Unknown	20 Milligram Daily;	Not Reported
Apo-Leflunomide	S	Unknown	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Celebrex	C	Oral	400 Milligram Daily;	Not Reported
Hydromorphone Hcl	C	Unknown		Not Reported
Celecoxib	C	Unknown		Not Reported
Methotrexate	C	Unknown	25 Milligram Daily;	Not Reported
Methotrexate	C	Unknown		Not Reported
Tylenol W/Codeine No.3	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	16119797	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-027001		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance; Dyspnoea; Eating Disorder; Eye Disorder; Fatigue; Infection; Intraocular Pressure Increased; Joint Swelling; Nausea; Ocular Hypertension; Ovarian Neoplasm; Pain In Extremity; Pneumonia; Rash; Unevaluable Event; Weight Decreased	Orencia			S	Unknown	Therapy Duration 10.0 Month(S)		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Therapy Duration 30 Days		Not Reported
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration 6.0 Years		Not Reported
	Leflunomide			S	Unknown	62.0 Days		Not Reported
	Methotrexate			S	Unknown	123 Days		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	16462022	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006323			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Apo-Acetaminophen			S	Unknown	Unk		Apotex
Abnormal; Condition	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
Aggravated; Drug	Hydroxychloroquine			S	Oral	200 Mg, Unk		Apotex
Ineffective; Drug	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
Intolerance; Fatigue; Gait	Apo-Prednisone			S	Unknown	20 Ng, Unk		Apotex
Disturbance; Joint	Leflunomide			S	Unknown	200 Mg, Qd		Apotex
Swelling; Loss Of	Leflunomide			S	Oral	20 Mg, Qd		Apotex
Personal Independence In	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
Daily Activities; Malaise;	Acetaminophen			S	Unknown	Unk		Not Reported
Nephrolithiasis; Off Label	W/Diphenhydramine							
Use; Pain; Pain In	Hydrochloride							
Extremity; Peripheral	Actemra			S	Subcutaneous	Unk		Not Reported
Swelling; Red Blood Cell	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
Sedimentation Rate								
Increased; Rheumatoid	Arava			S	Oral	20 Mg, Qd		Not Reported
Arthritis; Somnolence;	Arava			S	Oral	20 Mg, Qd		Not Reported
Visual Impairment	Arava			S	Unknown	10 Mg, Qd		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk (4 Every 1 Week)		Not Reported
	Enbrel			S	Unknown	40 Mg, Unk (4 Every 1 Week)		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.Wk.		Not Reported

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Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Orencia	S	Unknown	200 Mg, Unk	Not Reported
Orencia	S	Unknown	750 Mg, Unk	Not Reported
Plaquenil /00072602/	S	Oral	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	200 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	500 Mg, Bid	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Synthroid	C			Not Reported
Acetaminophen/Codein Phosphate	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	25 Df, Q.Wk.	Not Reported
Methotrexate	C	Unknown	Unk Unk, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	Unk, 4 Every 1 Week	Not Reported
Methotrexate	C	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	C	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Tylenol With Codeine No.3	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	20 Mg, Qd	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported

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	Celebrex	C	Unknown	Unk		Not Reported
	Xeljanz	C	Unknown	Unk		Not Reported
	Tylenol With Codein #3	C	Unknown	Unk		Not Reported

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04-May-2020	16641652	EXPEDITED (15-DAY)		OT	CA-ROCHE-2361846			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen;Codeine Phosphate			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17250187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513966		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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C-Reactive Protein Increased; Joint Swelling; Pneumonia; Treatment Failure	Actemra	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe, Solution Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Infliximab	S	Unknown		Not Reported
	Cefalexin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17454345	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP007815		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Apo-Lefflunomide			S	Unknown	Unk		Apotex	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituxan			S	Intravenous (not	Unk		Not Reported	

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		otherwise specified)			
Sulfasalazine	S	Unknown	500 Mg, Unk		Not Reported
Desoximetasone	C	Unknown	10 Mg, Qd		Not Reported
Diclofenac	C	Unknown	100 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17595157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020012294		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Cimzia			S	Subcutaneous	400 Milligram		Ucb
Adverse Drug Reaction;	Cetirizine Hydrochloride,			S	Unknown			Not Reported
Alopecia; Anti-Cyclic	Pseudoephedrine Hydrochloride							
Citrullinated Peptide	Cetirizine Hydrochloride,			S				Not Reported
Antibody Positive;	Pseudoephedrine Hydrochloride							
Arthralgia; Discomfort;	Cetirizine Hydrochloride			S		10 Milligram		Ucb
Drug Ineffective; Drug	Cetirizine Hydrochloride			S				Ucb
Intolerance; Fatigue;	Stelara			S	Subcutaneous	Unk		Not Reported
Glossodynia; Hand	Simponi			S	Subcutaneous	Unk		Not Reported
Deformity; Hepatic	Remicade			S	Subcutaneous	Unk		Not Reported
Enzyme Increased;	Cortisone Acetate			S				Not Reported
Hypersensitivity; Infusion	Cortisone Acetate			S		25 Milligram		Not Reported
Related Reaction; Joint	Desoximetasone			S	Oral	And Oral		Not Reported
Swelling; Maternal	Diclofenac			S				Not Reported
Exposure During	Enbrel			S	Subcutaneous	Unk		Not Reported
Pregnancy;	Folic Acid			S		5 Milligram		Not Reported
Musculoskeletal Stiffness;	Folic Acid			S	Oral	25 Milligram		Not Reported
Off Label Use; Pain;	Fosamax			S	Oral	Unk		Not Reported
Pemphigus; Pericarditis;	Fosamax			S	Oral	Unk		Not Reported
Product Use Issue; Rash;	Fosamax			S	Oral	Unk		Not Reported
Rheumatoid Arthritis;	Fosamax			S	Oral	Unk		Not Reported
Rheumatoid Factor	Humira			S	Subcutaneous	4 Milligram		Ucb
Positive; Synovitis;	Humira			S		40 Milligram		Ucb
Systemic Lupus								
Erythematous;								
Therapeutic Product Effect								
Decreased; Treatment								
Failure; Wound								

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Leflunomide	S		Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S		400 Milligram, Once Daily (Qd)	Not Reported
Pseudoephedrine Hcl	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S			Not Reported
Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
Sulfathalidine	S		Unk	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Unk	Not Reported
Topicort [Desoximetasone]	S	Topical	Unk	Not Reported
Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Milligram, 2x/Day (Bid)	Not Reported
Xeljanz	S		5 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S		Unk	Not Reported
Apo-Prednisone	S		40 Milligram	Not Reported
Apo-Prednisone	S			Not Reported
Arava	S		Unk	Not Reported
Salazopyrin	C			Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Subcutaneous	25 Unk	Not Reported

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04-May-2020	17662224	EXPEDITED (15-DAY)		DE, HO, OT	SK-GLAXOSMITHKLINE-SK2020061907		57 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Belimumab			S	Unknown	Unk		Glaxosmithkline	
	Azathioprine			S	Unknown	Unk		Glaxosmithkline	
	Cyclosporine A			S	Unknown	Unk		Glaxosmithkline	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Cyclophosphamide			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17674805	EXPEDITED (15-DAY)		DE, HO, OT	SK-ORION CORPORATION ORION PHARMA-20_00008910		57 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Jc Virus Infection; Mental Impairment; Pneumonia; Product Use In Unapproved Indication; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Cyclosporine A			S	Unknown			Not Reported	
	Belimumab			S	Unknown			Not Reported	
	Cyclophosphamide			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	

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Mycophenolate Mofetil

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17684289	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1038428		43 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Off Label Use; Pyrexia; Systemic Lupus Erythematosus; Therapy Non-Responder	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	12.5 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	15 Mg Qd, Dose Tapering		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Tacrolimus			S		1 Dosage Form, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Mylan
	Envarsus			S	Unknown	Unk, Qd		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
	Belimumab			S	Unknown	Unk		Mylan
Mycophenolate Mofetil			S	Unknown	1 Dosage Form, Qd		Mylan	
Rituximab			C		Unk		Mylan	
Methylprednisolone			C		Unk (Pulses)		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17696993	EXPEDITED (15-DAY)		HO, OT	BR-ADVANS PHARMA-202004003349			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hallucination; Off Label Use; Psychotic Disorder	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet		Concordia
	Hydroxychloroquine			S		200 Mg, Bid (Q12h Nasoenteric Probe), Coated Tablet		Concordia
	Azithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Metamizole Sodium			C		Unk		Not Reported
	Sodium Heparin			C		Unk		Not Reported
	Methylprednisolone Sodium Succinate			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Methadone Hydrochloride			C		Unk		Not Reported
	Piperacilina+Tazobactam			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17696996	EXPEDITED (15-DAY)		OT	FR-ADVANS PHARMA-202004003506			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Off Label Use	Hydroxychloroquine			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Fludrocortisone			C		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17722247	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032972			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Unknown			Not Reported	
	Diclofenac			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Phthalylsulphathiazole			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Reactine [Cetirizine			S	Unknown			Not Reported	

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Hydrochloride]
Simponi

S

Subcutaneous

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17737409	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589933		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angina Pectoris;	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
Arthralgia; Aspartate Amino	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
transferase Increased; Cardiac Murmur; Drug Intolerance;	Enbrel			S	Unknown			Not Reported
Dyspnoea Exertional; Fatigue; Hyperkeratosis; Interstitial Lung Disease; Joint Swelling;	Humira			S	Subcutaneous			Not Reported
Osteoarthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Rosuvastatin Calcium			C	Oral			Not Reported
	Nitroglycerin			C				Not Reported
	Gabapentin			C	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Clonazepam			C	Oral			Not Reported
	Desipramine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739425	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020-BI-02		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract;	Mobicox			S	Unknown			Boehringer Ingelheim
Diarrhoea; Dizziness;	Actemra			S	Unknown			Not Reported
Drug Ineffective; Drug	Gold			S	Unknown			Not Reported



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Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion	Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Decreased; Joint Swelling; Malaise; Mobility	Hydroxychloroquine	S	Unknown		Not Reported
Decreased; Muscular Weakness;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Musculoskeletal Pain; Musculoskeletal Stiffness;	Leflunomide	S	Unknown		Not Reported
Myalgia; Off Label Use; Pain; Pain In Extremity;	Meloxicam	S	Unknown		Not Reported
Peripheral Swelling; Pulmonary Toxicity; Rash	Methotrexate	S	Unknown		Not Reported
Maculo-Papular; Rash	Orencia	S	Unknown		Not Reported
Pruritic; Rheumatoid Arthritis; Rheumatoid	Depo-Medrol	C	Intra-articular	Dosage Form: Suspension Intra-Articular	Not Reported
Lung; Synovial Cyst; Synovitis; Tenosynovitis;	Diclofenac	C	Unknown		Not Reported
Treatment Failure; Viral Upper Respiratory Tract Infection	Pantoprazole Magnesium	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739591	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-021847		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram,1 Total		Not Reported	
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported	
	Kaletra			S				Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739633	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592035			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739649	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591873			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

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Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739663	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-02		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis;	Mobicox			S	Unknown			Boehringer Ingelheim
	Actemra			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Form Of Admin: Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depomedrol			C	Intramuscular	Form Of Admin: Suspension For Infusion		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported

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Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Plaquenil [Hydroxychloroquine Phosphate] Prednisone Xeljanz	C C C	Unknown Unknown Oral	Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739722	EXPEDITED (15-DAY)		HO, OT	BE-ADVANS PHARMA- 202004004406			Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemolysis; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739747	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245893		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Sun	
	Plaquenil			S	Oral	Unk		Not Reported	
	Lovenox			C	Oral	Unk		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739833	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1945		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Disorder; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	

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Simponi	S	Unknown	Not Reported
Flexeril	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Visanne	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739836	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1679		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Gait Disturbance; Joint Swelling; Muscular Weakness; Nerve Injury; Pain; Paraesthesia; Rheumatoid Arthritis; Sciatica; Spinal Stenosis; Therapeutic Response Decreased	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown	Q Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil			S	Unknown	Q Unk		Not Reported
	Plaquenil			S	Unknown			Not Reported
	Actonel Xr			C	Unknown	Every Unspecified Unit (Q)		Not Reported
	Baclofen			C	Unknown	Every Night (Hs)		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Vitamin D			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739897	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590110		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Condition Aggravated; Drug Intolerance; Hepatic	Actemra			S	Subcutaneous	8.0 Months		Not Reported	
	Azathioprine			S	Unknown			Not Reported	

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Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Ciclosporin	S	Unknown	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Esomeprazole Sodium	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Nicotinamide	S	Unknown	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Sarilumab	S	Subcutaneous	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Thiamine Hydrochloride	S	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739900	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245906		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Mg Dia ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740011	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS		31 YR	Female	IND

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INC.-2020-00693

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Hydroxychloroquine			S	Unknown	5 Milligram/Kilogram		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740014	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01594		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740015	NON-EXPEDITED		LT, OT	US-LUPIN PHARMACEUTICALS INC.-2020-01647		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin	
	R Chop			C	Unknown	Unk		Not Reported	
	Doxorubicin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740016	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2020-00911		83 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Nausea	Hydroxychloroquine			S	Unknown	Unk		Lupin	
	Methotrexate			C	Unknown	Unk		Not Reported	
	Leflunomide			C	Unknown	Unk		Not Reported	
	Sulfasalazine			C	Unknown	Unk Unk, Tid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740017	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-01472			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740069	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA- 202004004409			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hand Fracture; Hip Fracture; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Qd		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740109	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- 201812000036			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Drug Hypersensitivity; Drug Ineffective; Hypersensitivity; Insomnia; Loss Of Personal Independence In Daily Activities; Pain; Rheumatoid Arthritis; Stress At Work; Swelling	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia	
	Arava			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			C				Not Reported	
	Acetaminophen And Codeine Phosphate			C		Unk		Not Reported	
	Cimzia			C		Unk		Not Reported	
	Humira			C		Unk		Not Reported	
	Orencia			C		Unk		Not Reported	
	Actemra			C		Unk		Not Reported	

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Simponi	C	Unk	Not Reported
Lyrica	C	Unk	Not Reported
Arthrotec	C	Unk	Not Reported
Tylenol	C	Unk	Not Reported
Rabeprazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740123	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590820			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740137	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2020-DE-1229760		71 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Off Label Use	Hydroxychloroquine			S	Oral	1200 Milligram Daily;		Teva	
	Hydroxychloroquine			S		200 Milligram Daily;		Teva	
	Hydroxychloroquine			S				Teva	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740608	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012639			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia;	Diclofenac			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hand Deformity;	Arava	S	Oral	Not Reported
Intentional Product Use	Arava	S	Unknown	Not Reported
Issue; Maternal Exposure	Cetirizine Hydrochloride	S	Unknown	Not Reported
During Pregnancy; Off	Cimzia	S	Subcutaneous	Not Reported
Label Use; Pain;	Cortisone Acetate	S	Unknown	Not Reported
Pemphigus; Rheumatoid	Enbrel	S	Subcutaneous	Not Reported
Arthritis; Swelling;	Folic Acid	S	Unknown	Not Reported
Systemic Lupus	Folic Acid	S	Unknown	Not Reported
Erythematosis; Wound	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740669	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245901		63 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740724	EXPEDITED (15-DAY)		DE, OT	ES- GLAXOSMITHKLINE- ES2020073213		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Long Qt Syndrome; Sudden Death	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Tid		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, Qid		Glaxosmithkline
	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline
	Dolquine			S	Oral	400 Mg		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Cefotaxim			C	Intravenous drip	4 G, Bid		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Midazolam			C	Intravenous drip	100 Mg, Qd		Not Reported
	Ipratropii Bromidum			C	Respiratory (inhalation)	20 ?G		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740754	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA- GSH201907-001630			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chills; Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Epstein-Barr Virus Infection	Hydroxychloroquine	S	Unknown	Unk	Concordia
Reactivation; Face Oedema; Leukocytosis; Oedema Peripheral; Pyrexia; Rash; Rash; Rash; Rash Pruritic; Rebound Effect; Transaminases Increased	Hydroxychloroquine	S			Concordia
	Methylprednisolone	S	Unknown	60 Mg, Qid	Not Reported
	Methylprednisolone	S	Unknown	80 Mg, Bid	Not Reported
	Methylprednisolone	S	Oral	Unkunknown (Tapered To Oral Methylprednisolone)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740767	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591294			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C				Not Reported
	Caffeine			C				Not Reported
	Codeine Phosphate			C				Not Reported
	Meprobamate			C				Not Reported
	Dorzolamide Hydrochloride			C				Not Reported
	Timolol Maleate			C				Not Reported
	Folic Acid			C				Not Reported
	Levothyroxine			C				Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

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Ramipril		C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740826	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010325			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Microscopic; Gastrointestinal Disorder; Rash	Leflunomide			S	Unknown	20.0 Mg, Unk		Apotex	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Methotrexate			C	Subcutaneous	25 Mg, Q.Wk.		Not Reported	
	Sulfasalazine			C	Unknown	2.0 G, Unk		Not Reported	
	Xeljanz			C	Oral	5 Mg, Q.12h		Not Reported	
	Venlafaxine Hydrochloride			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591475			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			C				Not Reported	
	Wellbutrin			C	Unknown			Not Reported	
	Xeljanz			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588677		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amyotrophic Lateral Sclerosis; Contraindicated Product Administered; Multiple System Atrophy	Actemra			S	Intravenous (not otherwise specified)	Duration 7 Years		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Duration 579		Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Xeljanz			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Unknown	Cyclical Duration 2 Years		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral	1 In1 Week		Not Reported	
	Methotrexate			S	Subcutaneous	1 In1 Week		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	Duration:7.0 Months		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740840	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114283			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Desoximetasone			S	Oral			Sanofi	
	Leflunomide			S	Oral			Sanofi	
	Cetirizine Hydrochloride			S				Not Reported	
	Folic Acid			S				Not Reported	
	Alendronate Sodium			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S				Sanofi	

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Deformity; Maternal	Methotrexate	S	Oral		Not Reported
Exposure During	Plaquenil	S		400 MI, Qd	Sanofi
Pregnancy; Pain;	Prednisone	S			Not Reported
Pemphigus; Product Use	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Issue; Rash; Rheumatoid	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Arthritis; Swelling;	Orencia	S	Subcutaneous		Not Reported
Systemic Lupus	Adalimumab	S	Subcutaneous		Not Reported
Erythematous; Wound	Phthalylsulfathiazole	S			Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Tocilizumab	S			Not Reported
	Tofacitinib Citrate	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740849	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590808		33 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Actemra			S	Unknown			Not Reported
Seborrhoeic Dermatitis	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C	Oral			Not Reported
	Prednisone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740856	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591172		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741402	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591623			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Diclofenac Sodium			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Phthalylsulfathiazole			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution For Infusion		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591821		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache;	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Arthritis; Treatment Failure; Viral Infection	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741494	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC- 2020171727		28 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported	
	Ceftriaxone Paracetamol			S S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)		Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741579	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020171234		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	Unk		Pfizer	
	Hydroxyzine Arrow			S	Oral	25 Mg, Single		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	600 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741587	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171158		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Chest Discomfort; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741728	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-035310			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Ineffective; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Celecoxib			S	Oral	200 Milligram, Bid		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741744	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589836		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge; Spinal Operation; Sputum Discoloured; Therapeutic Product Effect Decreased; Thrombosis	Apo-Prednisone	S	otherwise specified)	Unknown	Not Reported
	Arava	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Humira	S	Subcutaneous	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unknown	Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Warfarin	S	Unknown	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741774	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591992			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Loss Of Personal Independence In Daily Activities;	Actemra			S	Unknown			Not Reported
Rheumatoid Arthritis;	Cimzia			S	Subcutaneous			Not Reported
Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Leflunomide	C		Not Reported
	Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590815			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Meloxicam			S	Oral			Not Reported
	Sulfasalazine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741908	EXPEDITED (15-DAY)		DS	CA-ROCHE-2590957		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Headache; Impaired Work	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ability; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Peripheral Swelling; Skin Mass	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742198	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1229970		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Leflunomide			S	Unknown			Barr
Blood Pressure Fluctuation; Blood	Methotrexate			S	Unknown			Barr
Pressure Increased;	Naproxen			S	Unknown			Teva
Depression; Drug	Anakinra			S	Unknown			Not Reported
Ineffective; Drug	Etanercept			S	Unknown			Not Reported
Intolerance; Flushing;	Hydroxychloroquine			S	Unknown			Not Reported
Heart Rate Decreased;	Infliximab			S	Unknown			Not Reported
Herpes Zoster; Impaired	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Healing; Infusion Related	Sulfasalazine			S	Unknown			Not Reported
Reaction; Joint Swelling;	Actemra			S	Intravenous (not			Not Reported
Localised Infection;								
Malaise; Medication Error;								
Nasopharyngitis; Pain;								
Peripheral Swelling; Rash;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non- Responder; Tooth Disorder; Toothache; Weight Increased	Acetaminophen Diphenhydramine Hydrochloride Ferrous Gluconate Folic Acid Lasix [Furosemide] Methylprednisolone Naprosyn [Naproxen] Oxycontin Oxyneo	C C C C C C C C C	otherwise specified)	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742199	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1229977		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Leflunomide Methotrexate Actemra Apo-Leflunomide Enbrel Humira Hydroxychloroquine Sulfate Orencia Remicade Rituximab Sulfasalazine Naproxen			S S S S S S S S S S S S C	Oral Unknown Intravenous (not otherwise specified) Unknown Unknown Subcutaneous Oral Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown			Barr Barr Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742242	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230038			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuropathy Peripheral	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Codeine Phosphate			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Azathioprine Sodium			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742305	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230007		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Leflunomide			S	Unknown			Barr	
	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Arthrotec			C				Not Reported	
	Azathioprine			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ergocalciferol

C

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742309	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230224			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown			Not Reported
Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742317	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230103			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

10 MI Daily;

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742319	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1229996		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash; Rheumatoid Arthritis	Leflunomide			S	Oral			Barr
	Cefazolin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C	Oral	10 Milligram Daily;			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742383	EXPEDITED (15-DAY)	OT		CA-ROCHE-2591127			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Headache; Hypersensitivity; Nausea; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sarilumab			S	Unknown			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Aluminum Acetate			C				Not Reported	
	Atacand			C	Unknown			Not Reported	
	Benzethonium Chloride			C				Not Reported	
	Neurontin			C	Unknown			Not Reported	
	Ergocalciferol			C				Not Reported	
	Folic Acid			C				Not Reported	
	Hydrodiuril			C				Not Reported	
	Premarin			C				Not Reported	
	Tylenol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742438	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1230239			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Blister; Drug Ineffective; Feeling	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Gastrointestinal Disorder; Hepatic Enzyme	Methotrexate	S	Unknown	Barr
Abnormal; Inappropriate Schedule Of Product	Arthrotec	S	Unknown	Not Reported
Administration; Mouth Haemorrhage; Mouth Ulceration;	Cimzia	S	Unknown	Not Reported
Musculoskeletal Discomfort; Nausea; Psoriatic Arthropathy; Pyrexia; Synovitis	Cosentyx	S	Unknown	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Lipitor	S	Oral	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Dovobet	C	Topical	Not Reported
	Flovent	C	Respiratory (inhalation)	Not Reported
	Folic Acid	C	Oral	Not Reported
	Multi Vitamin	C	Oral	Not Reported
	Omeprazole	C	Oral	Not Reported
	Ventolin	C	Respiratory (inhalation)	Not Reported
	Vitamin D2	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742609	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1043063			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: 10 Mg, Qd		Not Reported
	Kiovig			S	Transplacental	Unk		Mylan
	Hydroxychloroquine			S	Transplacental	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742756	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230080		75 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Parenteral			Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Penicillamine			C	Unknown			Not Reported
	Prednisone			C	Unknown	12 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Minocycline			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742810	EXPEDITED (15-DAY)		LT	CA-TEVA-2020-CA-1230043		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Arthropathy; C-Reactive	Leflunomide			S	Unknown			Barr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Protein Abnormal; C-Reactive Protein Increased;	Leflunomide	S		Barr
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Methotrexate Sodium	S	Unknown	Barr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling;	Methotrexate Sodium	S	Unknown	Barr
Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction;	Minocycline Hydrochloride	S	Unknown	Actavis
Pulmonary Embolism; Pulmonary Thrombosis;	Minocycline Hydrochloride	S	Unknown	Actavis
Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Oxycodone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Gold	S	Unknown	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17742993	EXPEDITED (15-DAY)		HO	SE-MYLANLABS-2020M1043195		16 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	750 Milligram		Not Reported	
	Prednisolone			S	Oral	10-15st.		Not Reported	
	Plaquenil /00072603/			S	Oral	10-15 St.		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17743520	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1230201			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product	Leflunomide			S	Unknown			Barr	
	Leflunomide			S				Barr	
	Oxycodone			S	Unknown			Actavis	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Methotrexate Sodium			S	Unknown			Barr	
	Methotrexate Sodium			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Actemra			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Use Issue; Interstitial Lung Disease; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Red Blood Cell Sedimentation Rate	Anakinra	S	Unknown	Not Reported
Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Thrombosis; Urticaria	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Marijuana	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine
Xeljanz

S
S Oral

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17743532	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230195		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Lung Disorder; Musculoskeletal Stiffness; Pain; Palpitations; Red Blood Cell Sedimentation Rate Abnormal; Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Rituximab			S	Unknown			Not Reported
Sulfasalazine			S	Unknown		2 Gram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17743534	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1230217		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin;	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
Methotrexate			S	Subcutaneous			Barr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypercalcaemia;	Methotrexate	S	Subcutaneous	Barr
Hypersensitivity;	Methotrexate	S	Unknown	Barr
Inflammation; Infusion	Methotrexate	S	Unknown	Barr
Related Reaction; Loss Of	Methotrexate	S	Unknown	Barr
Personal Independence In	Methotrexate	S	Unknown	Barr
Daily Activities;	Methotrexate	S	Unknown	Barr
Panniculitis; Peripheral	Methotrexate	S	Unknown	Barr
Swelling; Rash; Rash	Methotrexate	S	Subcutaneous	Barr
Pruritic; Red Blood Cell	Methotrexate	S	Subcutaneous	Barr
Sedimentation Rate	Methotrexate	S	Unknown	Barr
Increased; Rheumatoid	Methotrexate	S	Unknown	Barr
Arthritis; Rheumatoid	Alendronate Sodium	S	Unknown	Actavis
Nodule; Skin Necrosis;	Codeine	S	Unknown	Not Reported
Skin Ulcer; Therapeutic	Actemra	S	Unknown	Not Reported
Response Decreased;	Actemra	S	Unknown	Not Reported
Ulcer	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Oral	Not Reported

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	Prednisone			C					Not Reported
	Xeljanz			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17743538	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230200		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Parenteral			Barr	
	Adalimumab			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Azathioprine			C	Unknown			Not Reported	
	Ciclosporin			C	Unknown			Not Reported	
	Minocycline			C	Unknown			Not Reported	
	Penicillamine			C	Unknown			Not Reported	

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Prednisolone	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17743552	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230190		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Joint Swelling; Mouth Ulceration; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	5 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
Prednisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17743595	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230196		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass;	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Factor Positive	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Azathioprine	C	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Gold	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745001	DIRECT	Y	DE			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Hydroxychloroquine			S	Oral			Actavis	
	Actemra	Y		S	Intravenous bolus	Other Frequency:X1;		Genentech	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745146	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230094		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Tenofovir	C	Unknown	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745147	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230084			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Dyspnoea; Hypertension; Neoplasm Malignant	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745151	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230198		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma	Leflunomide	S	Oral		Barr
	Leflunomide	S	Unknown		Barr
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Desoximetasone	C	Unknown	10 Milligram Daily;	Not Reported
	Diclofenac	C	Unknown	100 Milligram Daily;	Not Reported
	Methotrexate	C	Unknown		Not Reported
	Voltaren [Diclofenac]	C	Unknown	100 Milligram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zostavax	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745152	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230102		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Leflunomide			S	Unknown			Barr	
Arthralgia; Diarrhoea;	Leflunomide			S	Unknown			Barr	
Drug Hypersensitivity;	Leflunomide			S	Unknown			Barr	
Drug Ineffective; Infection;	Methotrexate			S	Subcutaneous			Barr	
Lower Respiratory Tract Infection; Nausea;	Methotrexate			S	Subcutaneous			Barr	
Palpitations; Pulmonary Mass; Rheumatoid Arthritis	Methotrexate			S	Unknown			Barr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Arthrotec	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Imuran [Azathioprine]	C	Unknown	Not Reported
Vitamin D [Colecalciferol]	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745153	EXPEDITED (15-DAY)		DE, LT	CA-TEVA-2020-CA-1230049		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Leflunomide			S	Unknown			Barr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein	Leflunomide			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased;	Methotrexate	S	Unknown	Barr
Contraindicated Product	Methotrexate	S		Barr
Administered; Deep Vein	Methotrexate Sodium	S	Unknown	Barr
Thrombosis; Diverticulitis;	Minocycline	S	Unknown	Actavis
Drug Hypersensitivity;	Minocycline Hydrochloride	S	Unknown	Actavis
Drug Ineffective; Drug	Oxycodone	S	Unknown	Actavis
Intolerance; Feeling	Actemra	S	Unknown	Not Reported
Abnormal; Haemoglobin	Actemra	S	Unknown	Not Reported
Decreased; Herpes	Anakinra	S	Unknown	Not Reported
Zoster; Intentional Product	Anakinra	S		Not Reported
Use Issue; Interstitial Lung	Arava	S	Unknown	Not Reported
Disease; Joint Swelling;	Arava	S		Not Reported
Myocardial Infarction; Off	Enbrel	S	Subcutaneous	Not Reported
Label Use; Pain;	Enbrel	S		Not Reported
Photosensitivity Reaction;	Gold	S	Unknown	Not Reported
Pulmonary Embolism;	Gold	S		Not Reported
Pulmonary Thrombosis;	Humira	S	Subcutaneous	Not Reported
Red Blood Cell	Humira	S	Unknown	Not Reported
Sedimentation Rate	Hydroxychloroquine	S	Unknown	Not Reported
Increased; Renal Failure;	Hydroxychloroquine	S	Unknown	Not Reported
Sepsis; Stomatitis;	Marijuana	S	Unknown	Not Reported
Terminal State;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Thrombosis; Urticaria	Orencia	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Ilaris	C	Unknown	Not Reported
Ilaris	C	Subcutaneous	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745154	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230199			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745155	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1230197		53 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Therapeutic Response Decreased; Ulcer	Leflunomide			S	Oral			Barr
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Codeine Sulfate			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tocilizumab	S	Unknown		Not Reported
Ciclosporin	C	Unknown	150 Milligram Daily;	Not Reported
Prednisone	C	Unknown	10 Milligram Daily;	Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745157	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020017803			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Xeljanz			S				Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Tofacitinib			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745174	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144- 3388205-00		68 YR	Female	ESP

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Renal Impairment	Kaletra 200/50			S	Oral			Not Reported
	Ciclosporina			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745245	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034937		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bronchitis; Cough; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass; Nodule; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Orencia			S	Unknown			Bristol Myers Squibb
	Actonel			S	Oral	35 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported
	Methotrexate			S	Oral	22.5 Milligram, Qwk		Not Reported
	Novo-Rythro			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bupropion			C	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Celebrex			C	Unknown	200 Milligram, Bid		Not Reported
	Ergocalciferol			C	Unknown	Unk, Qd		Not Reported
	Hydroxychloroquine			C	Oral	400 Milligram, Qd		Not Reported
	Wellbutrin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745333	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2020-022011		56 YR	Female	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Hypoacusis	Azithromycin			S	Oral	500 Milligram, Once A Day, (500 Mg Dia)		Aurobindo
	Hidroxicloroquina			S	Oral	400 Milligram, Once A Day, (400 Mg Dia)		Not Reported
	Hidroxicloroquina			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745350	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232076		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			C		300 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17745363	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232129		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Leflunomide			S	Unknown	1 Dosage Forms Daily;		Barr
	Methotrexate			S	Subcutaneous			Barr
	Risedronate Sodium			S	Unknown			Teva

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown 1 Dosage Forms Daily;	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	12326256	EXPEDITED (15-DAY)		OT	CA-ROCHE-1750136		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Arthropathy; Bone Cyst; Bone Erosion; C-Reactive Protein Abnormal; Diabetes Mellitus; Drug Ineffective; Hepatic Steatosis; Hypertension; Joint Ankylosis; Joint Swelling; Liver Disorder; Musculoskeletal Stiffness; Osteolysis; Pain; Red Blood Cell Sedimentation Rate Abnormal; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Upper Respiratory Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral	Therapy Duration: 365 Nos		Not Reported	
	Arava			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	Therapy Duration: 880 Days		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate Sodium			S	Oral	Therapy Duration: 20 Years		Not Reported	
	Methotrexate Sodium			S	Oral			Not Reported	
	Methotrexate Sodium			S	Subcutaneous			Not Reported	
	Methotrexate Sodium			S	Oral			Not Reported	
	Methotrexate Sodium			S	Oral	12.0 Months		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Oral	20.0 Years	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Cortisone	C	Unknown		Not Reported
Desoximetasone	C	Unknown		Not Reported
Infliximab	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	12590542	EXPEDITED (15-DAY)		OT	CA-ROCHE-1627133		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Arava			S	Oral	Frequency: Every 1 Day		Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Every Day Besides Sunday		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	13067385	EXPEDITED (15-DAY)		OT	CA-ROCHE-1871931			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	13187329	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886111		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Contusion; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity; Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Spinal Disorder; Spinal Operation; Swelling; Therapy Non-Responder	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	13519755	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-038176		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; General Physical Health Deterioration; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Live Birth; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis;	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Oral	20 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Desoximetasone			S	Oral	Unk		Not Reported
	Desoximetasone			S	Unknown	Unk		Not Reported
	Desoximetasone			S	Unknown	25 Milligram		Not Reported
	Desoximetasone			S	Cutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Rheumatoid	Desoximetasone	S	Oral	Unk	Not Reported
Arthritis; Rheumatoid	Desoximetasone	S	Unknown	Unk	Not Reported
Factor Positive; Swelling;	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
Synovitis; Systemic Lupus	Enbrel	S	Subcutaneous	Unk	Not Reported
Erythematosis; Treatment	Enbrel	S	Unknown	Unk	Not Reported
Failure; Wound	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	500 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Folic Acid	S	Oral	1 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Oral	400 Milligram, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S	Oral	20 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	1 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Oral	10 Milligram	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	20 Milligram	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Oral	500 Milligram	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Urethral	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Oral	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram, Qd	Not Reported
Apo-Prednisone	S	Unknown	5 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Hydroxychloroquine Phosphate	S	Oral	400 Milligram, Qd	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Apo-Folic Acid	S	Unknown	15 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	25 Milligram	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown	50 Milligram	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
Cortisone Acetate	S	Topical	25 Milligram	Not Reported
Cortisone Acetate	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Oral	Unk	Not Reported
Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
Methotrexate Sodium	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Other	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Oral	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	40 Milligram, Qd	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	20 Milligram	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Etanercept	S	Subcutaneous	Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Leflunomide	C	Oral	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown		Not Reported
Lisinopril	C	Unknown		Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown		Not Reported
Diclofenac	C	Unknown	Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	13939230	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017490		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Apo-Leflunomide			S	Oral	Unk		Apotex
Abdominal Pain Upper;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
Aggression; Alopecia;	Leflunomide			S	Unknown	Unk		Apotex
Anxiety; Arthralgia;	Enbrel			S	Unknown	Unk		Not Reported
Asthenia; Blood Creatinine Increased; Cough;	Humira			S	Subcutaneous	Unk		Not Reported
Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspnoea;	Methotrexate Sodium			S	Unknown	Unk		Not Reported
Dyspnoea; Increased Upper Airway Secretion; Insomnia; Joint Swelling; Lung Disorder;	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
Malaise; Off Label Use; Peripheral Swelling;	Prolia			S	Subcutaneous	Unk		Not Reported
Productive Cough;	Methotrexate			S	Unknown	Unk		Not Reported
Retinopathy; Secretion Discharge; Sinus Disorder; Sinusitis; Synovitis;	Xeljanz			C	Oral	5 Mg, Bid		Not Reported
Tachyphylaxis; Urinary Tract Infection	Cymbalta			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	13958227	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017824		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Hydroxychloroquine			S	Oral	Unk, Qd		Apotex
Drug Ineffective; Joint Swelling; Pain	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Actemra			S	Unknown			Not Reported
	Lyrica			S	Oral	Unk, Bid		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Tylenol /00020001/	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	13967555	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017891		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	14241987	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021746		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Apo-Leflunomide	S	Oral	20 Mg, Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Varenicline Tartrate	S	Oral	1 Df, Qd	Not Reported
	Varenicline Tartrate	S	Oral	Unk Unk, Q.Wk.	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Valtrex	C	Oral	1000 Mg, Bid	Not Reported
	Valtrex	C			Not Reported
	Rosuvastatin Calcium	C	Oral	Unk Unk, Qd (Once Every 24 Hours)	Not Reported
	Esomeprazole Magnesium W/Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Oral	Unk	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Oral	500 Mg, Bid	Not Reported
	Naproxen	C	Oral	500 Mg, Bid	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	14746347	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP009094		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex	

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Ineffective; Drug	Hydroxychloroquine	S			Apotex
Intolerance; Headache;	Leflunomide	S	Unknown	20 Mg, Qd	Apotex
Off Label Use;	Actemra	S	Unknown		Not Reported
Rheumatoid Arthritis;	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Therapeutic Product Effect	Orencia	S	Unknown	40 Mg/Kg, Q.O.Wk.	Not Reported
Incomplete; Tremor	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	S	Oral	2.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	15 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	1 Df, Q.Wk.	Not Reported
	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Unknown	Unk	Not Reported
	Pantoprazole Magnesium	C	Oral	40 Mg, Qd	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	300 Mg, Unk	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	300.0 Mg, Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Zopiclone	C	Unknown	7.5 Mg, Qd	Not Reported
	Folic Acid	C	Oral	2.5 Mg, Qd	Not Reported
	Folic Acid	C			Not Reported
	Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	14815367	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712238		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Condition Aggravated;	Actemra			S	Unknown	Therapy Duration: 2 Years		Not Reported
Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Year(S)		Not Reported
Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis;	Anakinra			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Anakinra			S	Subcutaneous	Therapy Duration: 3 Years		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 2 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 2 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral	Duration: 8.0 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Methotrexate Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	14917304	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-093137		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Orencia			S	Unknown			Bristol Myers Squibb
Arthropathy; Condition	Methotrexate Sodium			S	Unknown	Unk		Not Reported
Aggravated; Deformity;	Humira			S	Subcutaneous	Unk		Not Reported
Diarrhoea; Disease	Celebrex			S	Unknown	Unk		Not Reported
Progression; Drug	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
Ineffective; Drug	Apo-Warfarin			S	Unknown	Unk		Not Reported
Interaction; Embolism;	Enbrel			S	Unknown	Unk		Not Reported
Fear; Fine Motor Skill	Enbrel			S	Unknown			Not Reported
Dysfunction; Finger	Anakinra			S	Unknown	Unk		Not Reported
Deformity; Hand	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Deformity; Impaired	Phosphate]							
Healing; Musculoskeletal	Methotrexate			S	Unknown	Unk		Not Reported
Disorder; Nausea; Pain;	Warfarin			S	Unknown	Unk		Not Reported
Rash; Rheumatoid	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Arthritis; Swelling;								
Therapeutic Product Effect								
Decreased; Therapeutic								
Product Effect Incomplete								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15050148	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021593		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Leflunomide			S	Unknown	20 Mg, Every 1 Day		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, Bid		Not Reported
	Enbrel			S	Unknown	25 Mg, 2 Every 1 Weeks		Not Reported
	Enbrel			S	Unknown	25 Mg, 1 Every 2 Weeks		Not Reported
	Humira			S	Unknown	40 Mg, 1 Every 2 Weeks For 4 Months And 6 Months		Not Reported
	Humira			S	Unknown	40 Mg, Cyclical		Not Reported
	Humira			S	Unknown	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk. (Therapy Duration: 790 Unit Unspecified)		Not Reported
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, 1 Every 6 Weeks		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk (Therapy Duration: 790 Unit Unspecified)		Not Reported
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	200 Mg, Q.Wk.		Not Reported
	Wellbutrin			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	1 G, Bid		Not Reported

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Sulfasalazine	C		Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15076484	EXPEDITED (15-DAY)		CA, OT	CA-APOTEX-2018AP015974			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Adalimumab			S	Subcutaneous	40 Mg, Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 14 Days		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk 1 Every 10 Days		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk 1 Every 14 Days		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tofacitinib			S	Unknown	Unk		Not Reported

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Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Kevzara	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1 G, Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Rabeprazole Sodium	C	Oral	20 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15331158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176740		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prevacid			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15386769	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- 20713376		28 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anovulatory Cycle;	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb	
Bronchitis;	Metformin Hydrochloride			S	Unknown	Unk		Bristol Myers Squibb	
Dermatomyositis; Drug	Metformin Hydrochloride			S	Unknown			Bristol Myers Squibb	
Ineffective; Gait Inability;	Cymbalta			S	Unknown	Unk		Not Reported	
Haemorrhage; Hepatic	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Cirrhosis; Hepatic Enzyme	Plaquenil [Hydroxychloroquine			S	Unknown	Unk		Not Reported	
Increased; Impaired Work	Phosphate]								
Ability; Intentional Product	Prednisone			S	Unknown	Unk		Not Reported	
Use Issue; Joint Range Of	Rituximab			S	Intravenous (not	1000 Milligram		Not Reported	
Motion Decreased;					otherwise specified)				
Malaise; Nasopharyngitis;	Rituxan			S	Intravenous (not	1000 Mg, Unk		Not Reported	
Nausea; Off Label Use;					otherwise specified)				
Pain; Thrombosis; Uterine	Sulfasalazine			S	Unknown	Unk		Not Reported	
Disorder; Weight	Imuran [Azathioprine]			C	Unknown	Unk		Not Reported	
Increased	Methotrexate			C	Unknown	Unk		Not Reported	
	Xarelto			C	Unknown	Unk		Not Reported	
	Azathioprine Sodium			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15412303	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186769			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug	Rituxan			S	Intravenous (not			Not Reported	
Intolerance; Feeding					otherwise specified)				
Disorder; Rheumatoid	Actemra			S	Unknown			Not Reported	
Arthritis; Stomatitis;	Cimzia			S	Subcutaneous			Not Reported	
Weight Decreased									

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Enbrel	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Varenicline Tartrate	S	Oral	Not Reported
Varenicline Tartrate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Valtrex	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Acetaminophen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15450369	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190759			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C	Unknown	Dosage Forms : 1.0		Not Reported

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Prednisone	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	15619576	EXPEDITED (15-DAY)		HO, OT	GR-ACCORD-091884		56 YR	Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Methotrexate			S	Unknown	15 Mg, Qw		Accord
	Citalopram			S	Unknown			Not Reported
	Captopril			S				Not Reported
	Alprazolam			S	Unknown			Not Reported
	Folic Acid			S	Unknown	5 Mg, Qw		Not Reported
	Etanercept			S	Unknown	Unk		Not Reported
	Hydroxychloroquine/Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Phosphate/Hydroxychloroquine Sulfate							
	Adalimumab			S				Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Valsartan			C				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	16359788	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03160		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram, Qd		Lupin
	Losartan			C	Unknown	100 Milligram, Qd		Not Reported

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05-May-2020	16691209	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208308			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Leflunomide			S	Unknown	10 Mg, Qd		Sanofi
	Methotrexate			S	Unknown	15 Mg, Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Unk		Sanofi
	Rituximab			S	Unknown	Unk Unk, Unk		Not Reported
	Remicade			S	Unknown	Unk Unk, Unk		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	16696905	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2019SA208335		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk, Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Leflunomide			S	Oral	Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi
	Hydroxychloroquine			S		Unk Unk, Unk		Sanofi

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Sedimentation Rate	Hydroxychloroquine	S		Unk Unk, Unk	Sanofi
Increased; Renal Failure;	Hydroxychloroquine	S	Oral	Unk Unk, Unk	Sanofi
Sepsis; Terminal State;	Methotrexate	S		Unk Unk, Unk	Not Reported
Thrombosis	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk Unk, Unk	Not Reported
	Plaquenil	S		Unk Unk, Unk	Sanofi
	Plaquenil	S		Unk Unk, Unk	Sanofi
	Sulfasalazine	S		Unk Unk, Unk	Not Reported
	Sulfasalazine	S		500 Mg, Unk	Not Reported
	Sodium Aurothiomalate	S		Unk Unk, Unk	Not Reported
	Sodium Aurothiomalate	S		Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk	Not Reported
	Anakinra	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Gold	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S		Unk Unk, Unk	Not Reported
	Humira	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Ilaris	S	Subcutaneous	Unk Unk, Unk	Not Reported
	Orencia	S		Unk Unk, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Remicade	S		Unk Unk, Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Rituxan	S		Unk Unk, Unk	Not Reported

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Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
Rituximab;Urelumab	C		Unk Unk, Unk	Not Reported

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05-May-2020	16884494	EXPEDITED (15-DAY)	OT		CA-ROCHE-2417965		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mol		Not Reported
	Wellbutrin			C	Unknown	Tablet (Extendedrelease)		Not Reported
	Sulfasalazine			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17241867	EXPEDITED (15-DAY)	OT		CA-ROCHE-2511098		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Tocilizumab	S	Unknown	Not Reported
	Anakinra	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17245016	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2511679		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Jaundice; Joint Swelling; Nausea; Platelet Count Increased; Rheumatoid Arthritis; Treatment Failure; Vitamin D Decreased; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Rosuvastatin	C	Unknown	Not Reported
	Vitamin C [Ascorbic Acid]	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Ergocalciferol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17259884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518729		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non- Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17278764	EXPEDITED (15-DAY)		OT	NVSC2019CA086426		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac			S	Unknown	50 Mg		Novartis
Alopecia; Anti-Cyclic Citruinated Peptide	Diclofenac Sodium			S	Unknown	Unk		Novartis
Antibody Positive;	Diclofenac Diethylamine			S	Unknown	Unk		Novartis
Arthralgia; Arthropathy; Blood Cholesterol Increased; Condition	Cetirizine Hydrochloride			S	Unknown	10 Mg		Not Reported
Aggravated;	Methotrexate			S	Oral	25 Mg		Not Reported
Contraindicated Product	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported
Administered; Decreased Appetite; Discomfort; Drug	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Drug Intolerance; Exposure During Pregnancy;	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Fatigue; General Physical Health Deterioration;	Folic Acid	S	Unknown	5 Mg	Not Reported
Glossodynia; Hand Deformity; Headache;	Folic Acid	S	Unknown	1 Mg	Not Reported
Hepatic Enzyme Increased;	Folic Acid	S	Unknown	0.5 Unk	Not Reported
Hypersensitivity;	Folic Acid	S	Oral	25 Unk	Not Reported
Hypertension;	Prednisone	S	Unknown	Unk	Not Reported
Hypoaesthesia; Infusion Related Reaction; Joint Swelling; Live Birth;	Etanercept	S	Subcutaneous	50 Mg	Not Reported
Malaise; Mobility Decreased;	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Musculoskeletal Stiffness; Off Label Use; Pain;	Cimzia	S	Subcutaneous	400 Mg	Not Reported
Pemphigus; Pericarditis;	Cimzia	S			Not Reported
Product Use Issue; Rash;	Remicade	S	Intravenous (not otherwise specified)	400 Mg, Qw	Not Reported
Rheumatic Fever;					
Rheumatoid Arthritis;	Simponi	S	Subcutaneous	50 Mg, Qw	Not Reported
Rheumatoid Factor Positive; Swelling; Swollen Joint Count Increased;	Enbrel	S	Subcutaneous	50 Mg	Not Reported
Synovitis; Systemic Lupus Erythematosus;	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus; Wound	Humira	S	Subcutaneous	40 Mg, Qw	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Biw	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Unknown	Unk	Not Reported
	Apo Prednison	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	400 Mg, Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400 Mg, Qd	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Salazopyrine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Sulfasalazine	S	Oral	1000 Mg, Qd	Not Reported
Paracetamol	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Tocilizumab	S	Subcutaneous		Not Reported
Winpred	S	Oral		Not Reported
Stelera	S	Unknown		Not Reported
Topicort	S	Subcutaneous		Not Reported
Topicort	S	Oral	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17396502	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-007504			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Drug Ineffective; Glossodynia; Maternal Exposure During	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Diclofenac	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Etanercept	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17594370	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA085524		57 YR	Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S				Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Ilaris			S	Subcutaneous	Unk		Novartis	
	Actemra			S	Unknown	Unk		Not Reported	
	Anakinra			S	Unknown	Unk		Not Reported	
	Anakinra			S				Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Arava			S				Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Gold			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Hidroxicloroquina			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Remicade			S	Unknown			Not Reported	
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	500 Mg, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17598822	EXPEDITED (15-DAY)		LT	NVSC2020CA085528		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Myocardial Infarction; Off Label Use; Pain;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Ilaris			S	Subcutaneous			Novartis	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S				Not Reported	
	Actemra			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Anakinra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unknown	Not Reported
	Urelumab	C	Unknown		Not Reported
	Rituximab	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17640700	EXPEDITED (15-DAY)		LT, OT	FR-SA-2020SA087400		18 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate			S	Other	1200 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S	Other	400 Mg, Qd		Sanofi	
	Lovenox			S	Subcutaneous	0.6 MI, Qd		Sanofi	
	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/MI, Qd		Not Reported	
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported	
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported	
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported	
	Movicol [Macrogol]			S	Other	2 Df Bag		Not Reported	

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3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch Paracetamol	C	Other	4 G, Qd	Not Reported
Paracetamol	C			Not Reported
Lasilix [Furosemide]	C	Other	30 Mg, Qd	Not Reported
Novorapid	C	Intravenous (not otherwise specified)	Unk	Not Reported
Doliprane	C			Not Reported
Doliprane	C			Not Reported
Diffu K	C	Other	3.6 G, Qd	Not Reported
Diffu K	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17662286	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-ADVANSZ PHARMA-202003002885			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; General Physical Health Deterioration; Off Label Use; Pneumonia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17688286	EXPEDITED (15-DAY)		OT	JP-ABBVIE-20K-087-3369108-00		58 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Gastrointestinal Disorder; General Physical Health Deterioration; Off Label Use	Kaletra			S	Oral	800 / 200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17708221	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA-202003002358			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Off Label Use; Pneumonia; Respiratory Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	At 800mg Loading Dose (400 Mg, Bid (Fiim-Coated Tablet)		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia	
	Enoxaparin			C		Unk		Not Reported	
	Enoxaparin			C				Not Reported	
	Paracetamol			C		Unk		Not Reported	
	Etomidate			C		Unk		Not Reported	
	Celocurine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17715835	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245249		52 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Paracetamol			S	Oral	1gr Cada 8 Horas		Ohm Lab	
	Simvastatina Alter 10 Mg Comprimidos Recubiertos Con Pelicula Efg ...			S	Oral	0-0-1 ()		Not Reported	
	Dolquine 200 Mg Comprimidos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17727001	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA-202004004251			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Respiratory Tract Infection Fungal	Hydroxychloroquine			S	Oral	600 Mg, Qd, Film-Coated Tablet		Concordia	

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Hydroxychloroquine	S	Oral	400 Mg, Qd, Film-Coated Tablet	Concordia
Imipenem	C		Unk	Not Reported
Lansoprazole	C		Unk	Not Reported
Enoxaparin	C		Unk	Not Reported
Chlorpromazine	C		Unk	Not Reported
Dexmedetomidine	C		Unk	Not Reported
Insulin	C		Unk	Not Reported
Urapidil	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17731811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590211			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Urethral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17732418	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245759		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Propofol 2% Injectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedacion		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	
	Dexametasona (722a)			C	Intravenous (not otherwise specified)	4 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17741948	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2020-021386		78 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742093	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-035046		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cough; Drug Ineffective; Headache; Product Use Issue; Rheumatoid Arthritis; Viral Infection	Abatacept			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Celebrex			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Subcutaneous	25 Milligram, Qwk		Not Reported	
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported	

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Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Xeljanz	S	Oral	50 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742136	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231902		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S	Unknown			Barr
	Risedronate Sodium			S	Unknown			Teva
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	300 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742350	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202004004645			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antiphospholipid Syndrome	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742372	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245940		78 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligrams, Daily		Sun
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	600 Milligrams, Daily		Not Reported
	Effexor L.P. 75 Mg, Gelule A Liberation Prolongee			S	Oral	150 Milligrams, Daily		Not Reported
	Acebutolol (Chlorhydrate D')			C	Oral	400 Milligrams, Daily		Not Reported
	Oxazepam			C	Oral	100 Milligrams, Daily		Not Reported
	Enoxaparine Sodique ((Mammifere/Porc/Muqueuse Intestinale))			C	Subcutaneous	4000 International Unit, Daily		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form, Daily		Not Reported
	Amlodipine			C	Oral	10 Milligrams, Daily		Not Reported
	Chlorhydrate De Clomipramine			C	Oral	150 Milligrams, Monthly		Not Reported
	Zopiclone			C	Oral	7.5 Milligrams, Daily		Not Reported
	Chlorhydrate De Nicardipine			C	Oral	60 Milligrams, Daily		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligrams, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742377	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245925		59 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Daily		Sun
	Loxapine Base			S	Oral	155 Milligrams, Daily		Not Reported
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	600 Milligrams, Daily		Not Reported
	Theralene			S	Oral	50 Milligrams, Daily		Not Reported
	Paracetamol			C	Oral	1 Grams, Daily		Not Reported
	Nicopatch 7 Mg/24 H, Dispositif Transdermique De 17,5 Mg/10 Cm^2			C	Transdermal	7 Milligrams, Daily		Not Reported
	Diazepam			C	Oral	10 Milligrams, Daily		Not Reported

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Atorvastatine	C	Oral	40 Milligram, Daily	Not Reported
Nicotine	C	Oral	12 Milligram, Daily	Not Reported
Macrogol 4000	C	Oral	Unk	Not Reported
Nebivolol	C	Oral	7.5 Milligrams, Daily	Not Reported
Zopiclone	C	Oral	7.5 Milligram, Daily	Not Reported
Ramipril	C	Oral	1.25 Milligram, Daily	Not Reported
Akineton	C	Oral	4 Milligram, 1 Minute	Not Reported
Ezetimibe	C	Oral	10 Milligram, Daily	Not Reported
Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet- Dose	C	Oral	75 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591039			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration 823 Nos		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydromorphone Hcl	C		Not Reported
Methotrexate	C	Unknown	Not Reported
Meloxicam	C		Not Reported
Leflunomide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592060		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592094		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; C-	Actemra			S	Unknown			Not Reported

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Reactive Protein Increased; Diverticulitis; Drug Ineffective; Drug Intolerance; Infection; Synovitis	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742535	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004726			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cornea Verticillata	Hydroxychloroquine			S		600 Mg, Bid		Concordia	
	Everolimus			C		10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232090		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Leflunomide			S	Oral			Barr	
	Methotrexate			S	Unknown			Barr	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	

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Rituximab	S	Intravenous drip	Not Reported
Acetaminophen	C		Not Reported
Arava	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Elavil	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Imitrex [Sumatriptan]	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Premarin	C	Unknown	Not Reported
Sumatriptan Succinate	C	Unknown	Not Reported
Tenormin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232139		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	25 Milligram Daily;		Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	otherwise specified)	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
		Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742586	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232163			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Polyneuropathy	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742590	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232148			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

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Meloxicam			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742663	EXPEDITED (15-DAY)		DE, OT	IR-BEH-2020117003			Unknown	IRN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Foetal Heart Rate Decreased; Maternal Exposure Timing Unspecified; Maternal Exposure Timing Unspecified	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring	
	Oseltamivir			S	Oral			Not Reported	
	Ceftriaxone			S	Oral			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Kaletra			S	Oral			Not Reported	
	Oxygen			S	Unknown			Not Reported	
	Fentanyl			S	Unknown			Not Reported	
	Propofol			S	Unknown			Not Reported	
	Cisatracurium			S	Unknown			Not Reported	
	Red Blood Cells			S	Unknown	Unk		Not Reported	
	Red Blood Cells			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported	
	Plasma, Fresh Frozen			S	Unknown	2 Units		Not Reported	
	Norepinephrine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742670	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591905			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Celecoxib	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Unknown	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742768	EXPEDITED (15-DAY)		HO	CA-ROCHE-2592005		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Methotrexate			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742782	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-034928		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Oral	20 Milligram, 1 Every 1 Day		Not Reported	
	Arava			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous	20 Milligram, Qwk		Not Reported	
	Plaquenil S			S	Unknown			Not Reported	
	Prednisolone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Risedronate Sodium			S	Unknown	5 Milligram		Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Oral	500 Milligram		Not Reported	
	Cyclobenzaprine			C	Unknown	10 Milligram		Not Reported	
	Desoximetasone			C	Unknown	5 Milligram, 1 Every 1 Day		Not Reported	
	Leflunomide			C	Unknown			Not Reported	
	Prednisone Acetate			C	Unknown	5 Milligram, 1 Every 1 Day		Not Reported	
	Tylenol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588925		41 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17742971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591836			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743291	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590858			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Folic Acid	C		Not Reported
	Leflunomide	C		Not Reported
	Orencia	C		Not Reported
	Tofacitinib Citrate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743295	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232132		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743297	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245987		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported	

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Hidroxiclороquina (2143a)			S	Oral	200 Mg/12h			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743508	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591144		48 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743620	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246009		28 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
	Paracetamol			S	Intravenous (not otherwise specified)	1gr Cada 8 Horas		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743624	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246005		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock;	Azithromycin			S	Oral	500 Milligram, Daily		Sun	

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Tachyarrhythmia	Hidroxiclороquina Sulfato	S	Oral	200 Milligram, Daily	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	()	Not Reported
	Ceftriaxona	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743627	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-246048		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 G Dia		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743715	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591859			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; Synovitis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	

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Methotrexate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591858		49 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743721	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034889		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Pulmonary Fibrosis; Red Blood Cell	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Actonel			S	Unknown	35 Milligram, Qwk		Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram		Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Sedimentation Rate	Gold	S	Unknown		Not Reported
Abnormal; Rheumatoid	Humira	S	Subcutaneous	40 Milligram	Not Reported
Arthritis; Rheumatoid	Hydroxychloroquine	S	Unknown	300 Milligram, Qd	Not Reported
Factor Positive; Synovitis	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
	Plaquenil S	S	Unknown	300 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	5 Milligram, 2 Every 1 Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17743801	EXPEDITED (15-DAY)		HO, OT	CN-ADVANSZ PHARMA-202004004658			Unknown	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Hepatic Enzyme Increased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk,		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		One Week After The Patient Started Tiated Hydroxychloroquine		Concordia
	Doxycycline Hyclate			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17744109	EXPEDITED (15-DAY)		HO, LT	FR-MYLANLABS-2020M1043507		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin	S	Oral	500 Mg J1 Puis 250 Mg Par Jour	Not Reported
	Plaquenil /00072603/	S	Oral	600 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17744126	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590175		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17744353	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2020-01836		41 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Infarction; Intrapartum Haemorrhage; Maternal	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Adverse Event Reporting System

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Detailed Report

Exposure During
Pregnancy; Pelvic
Infection; Placenta
Accreta; Post Procedural
Complication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17744433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592105		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17744998	EXPEDITED (15-DAY)		OT	ES-SA-2020SA115661		60 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	60 Mg 24 Hours		Sanofi
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17745259	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020175440		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug-Induced Liver Injury	Azithromycin			S	Oral	500 Mg, Daily (500 Mg/24h)		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	2 G, Daily (2gr/24h)		Pfizer	
	Ceftriaxone			S				Not Reported	
	Ceftriaxone			S	Oral	200 Mg, 2x/Day (200 Mg/12h)		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17745263	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020175443		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported	
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17745649	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1230665			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Erythema; Gastric Ulcer; Hepatic Function Abnormal; Liver Function Test Increased; Skin Exfoliation	Amlodipine Besilate			S	Unknown			Barr	
	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Naproxen			S	Unknown			Not Reported	

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Sulfasalazine	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral 300 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17745843	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1228870		68 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Sumamed 500 Mg			S	Intravenous (not otherwise specified)	200 Mg		Not Reported	
	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg, The First Day 1000mg, Then 500mg, Therapy Lasted For 3 Days		Teva	
	Midazolam			C				Not Reported	
	Lopinavir/Ritonavir			C				Not Reported	
	Paracetamol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746040	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230156		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hyponatraemia	Levofloxacin (2791a)			S	Oral	500 Milligram Daily;		Teva	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily;		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746046	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020178138		27 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Sinus Bradycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746077	EXPEDITED (15-DAY)		LT	FR-PFIZER INC- 2020178133		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hypotension; Off Label Use; Product Use In Unapproved Indication; Sinus Bradycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746092	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591180		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Tofacitinib Citrate			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Leflunomide			S	Unknown			Not Reported		

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	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Acetylsalicylic Acid	C		Not Reported
	Cymbalta	C		Not Reported
	Hydromorphone	C		Not Reported
	Remicade	C		Not Reported
	Synthroid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746179	EXPEDITED (15-DAY)		DE, OT	IR-BEH-2020117006			Unknown	IRN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Foetal Heart Rate Decreased; Maternal Exposure Timing Unspecified; Maternal Exposure Timing Unspecified	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring
	Oseltamivir			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Oxygen			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Propofol			S	Unknown			Not Reported
	Cisatracurium			S	Unknown			Not Reported
	Red Blood Cells			S	Unknown	Unk		Not Reported
	Red Blood Cells			S	Unknown	Unk		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Plasma, Fresh Frozen			S	Unknown	2 Units		Not Reported
	Norepinephrine			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746206	EXPEDITED (15-DAY)		OT	IR-BEH-2020117007			Female	IRN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Death; Haemoglobin Decreased; No Adverse Event; Product Use In Unapproved Indication	Human Immunoglobulin (Inn)			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Csl Behring
	Oseltamivir			S	Oral			Not Reported
	Ceftriaxone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Oxygen			S	Unknown			Not Reported
	Oxygen			S				Not Reported
	Fentanyl			S	Unknown	Unk		Not Reported
	Propofol			S	Unknown	Injection For Intubation		Not Reported
	Propofol			S	Unknown	Infusion For Mechanical Ventilation		Not Reported
	Cisatracurium			S	Unknown			Not Reported
	Red Blood Cells			S	Unknown	1 Unit		Not Reported
	Red Blood Cells			S	Unknown	1 Unit		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Plasma, Fresh Frozen			S	Unknown	2 Units		Not Reported
	Norepinephrine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746335	EXPEDITED (15-DAY)		DE	US-SLATE RUN PHARMACEUTICALS- 20US000055			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Off Label Use	Azithromycin Usp			S	Intravenous (not otherwise specified)	Unk		Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk, Single		Not Reported
	Methotrexate			C	Unknown			Not Reported
	Steroids			C		Unk		Not Reported
	Steroids			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746449	DIRECT	Y	DE			69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase Increased; Asthenia; Blood Alkaline Phosphatase Increased; Blood Fibrinogen Increased; Blood Lactate Dehydrogenase Increased; Blood Potassium Decreased; Hypertension; Hypoxia; Lymphopenia; Pneumonia; Respiratory Failure; Serum Ferritin Increased; Type 2 Diabetes Mellitus	Hydroxychloroquine Sulfate Tablets			S	Oral			Teva
	Doxycycline			C				Not Reported
	Azithromycin			C				Not Reported
	Ceftriaxone			C				Not Reported
	Ampicillin			C				Not Reported
	Tocilizumab			C				Not Reported
	Ns 1000 MI			C				Not Reported
	Acetaminophen			C				Not Reported
	Albuterol Inhaler			C				Not Reported
	Ascorbic Acid			C				Not Reported
	Benazepril			C				Not Reported
	Enoxaparin			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Regular Insulin			C				Not Reported
	Neutraphos			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746494	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114129			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>



Detailed Report

Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral		Sanofi
	Diclofenac Sodium	S			Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Cetirizine	S			Not Reported
	Hydrochloride/Pseudoephedrine				
	Hydrochloride				
	Cetirizine	S			Not Reported
	Hydrochloride/Pseudoephedrine				
	Hydrochloride				
	Sulfasalazine	S		500 Mg	Not Reported
	Arava	S	Oral		Sanofi
	Hydroxychloroquine	S			Sanofi
	Hydroxychloroquine Sulfate	S			Sanofi
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Prednisone	S	Oral		Not Reported
	Pseudoephedrine Hydrochloride	S			Sanofi
	Prednisone	S			Not Reported
	Folic Acid	S		1 Mg	Not Reported
	Folic Acid	S		5 Unk	Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Adalimumab	S	Subcutaneous	40 Mg	Not Reported
	Cortisone Acetate	S	Topical	25 Mg	Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not		Not Reported

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Simponi	S	otherwise specified)	Not Reported
Tocilizumab	S	Subcutaneous	Not Reported
Xeljanz	C	Subcutaneous	Not Reported

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05-May-2020	17746917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592525			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17747080	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1043943		77 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Qd		Mylan
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17747258	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2592551			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17747361	EXPEDITED (15-DAY)		LT	FR-MYLANLABS- 2020M1044977		78 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Qd		Not Reported
	Effexor			S	Oral	150 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Acebutolol			C	Oral	400 Milligram, Qd		Mylan
	Oxazepam			C	Oral	100 Milligram, Qd		Mylan
	Enoxaparine Sodique			C	Subcutaneous	4000 International Unit, Qd		Mylan
	Macrogol 4000			C	Oral	2 Dosage Form, Qd		Mylan

FDA Adverse Event Reporting System

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Amlodipine	C	Oral	10 Milligram, Qd	Mylan
Clomipramine Hydrochloride	C	Oral	150 Milligram, Monthly	Mylan
Zopiclone	C	Oral	7.5 Milligram, Qd	Mylan
Nicardipine Hydrochloride	C	Oral	60 Milligram, Qd	Mylan
Hydrochlorothiazide	C	Oral	25 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17748223	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012927			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17748237	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012925		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline Hydrochloride	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	11862970	EXPEDITED (15-DAY)		OT	CA-ROCHE-1602815		69 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Carotid Arteriosclerosis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Herpes Zoster; Joint Swelling; Limb Discomfort; Malaise; Nausea; Nodule; Osteoarthritis; Rectal Haemorrhage; Thyroid Cancer	Actemra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 730 Nos		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Enbrel			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	12962974	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857489			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Knee Arthroplasty; Medical Device Implantation	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	12967628	EXPEDITED (15-DAY)		DS	CA-ROCHE-1857523			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Arthroplasty; Drug Ineffective; Foot Operation; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13057780	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2016AP015710		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13058749	EXPEDITED (15-DAY)	OT		CA-APOTEX-2016AP015733		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure	Leflunomide			S	Oral	20.0 Mg, Qd		Apotex
	Mefenamic Acid			S	Unknown	400 Mg, Bid		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported
	Enbrel			S	Unknown	1 Df, Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unknown		Not Reported
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Q.Wk.		Not Reported
	Methotrexate Sodium			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Oral	400 Mg, Unk (Therapy Duration 730 Unit Unspecified)		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk, Bid		Not Reported
Advil /00044201/			S	Unknown	400 Mg, Bid		Not Reported	
Arava			S	Unknown	20 Mg, Qd		Not Reported	
Sulfasalazine			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13063060	EXPEDITED (15-DAY)		OT	CA-ROCHE-1631753			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Liver Injury; Loss Of Personal Independence In Daily Activities; Migraine; Neck Pain; Nodule; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	Not Controlling Disease And Causing Debilitation And Inability To Perform Daily Activities		Not Reported	
	Humira			S	Subcutaneous	Didn'T Work And Patient Still Symptomatic		Not Reported	
	Leflunomide			S	Unknown	Didn'T Work And Patient Still Symptomatic		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Methotrexate			S	Unknown	Affected Liver Enzymes		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13099718	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876546			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma;	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatic Enzyme Increased;	Cimzia	S	Subcutaneous	Not Reported
Hypersensitivity;	Orencia	S	Unknown	Not Reported
Hypertension; Pneumonia;	Arava	S	Unknown	Not Reported
Skin Reaction; Synovitis;	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Thyroid Disorder;	Estradiol	C		Not Reported
Treatment Failure;	Furosemide	C		Not Reported
Vomiting	Valsartan	C		Not Reported
	Xalatan	C		Not Reported
	Dorzolamide	C		Not Reported
	Hydrochloride/Timolol Maleate			
	Atasol With Codeine-Caffeine	C		Not Reported
	Acetaminophen	C		Not Reported
	Ergocalciferol	C		Not Reported
	Estrogel	C		Not Reported
	Gravol	C		Not Reported
	Levaquin	C		Not Reported
	Potassium Chloride	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13254176	EXPEDITED (15-DAY)		HO	CA-ROCHE-1893244		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13254292	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006753		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cytology Abnormal; Drug Intolerance; Joint Swelling; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd, (Therapy Duration: 365 Unit Not Reported)		Apotex
	Apo-Leflunomide			S	Unknown	11.2 Mg, Qd (Therapy Duration: 365 Unit Not Reported)		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd, Thepay Duration 365 Unit Not Reported		Apotex
	Sulfasalazine			S	Unknown	1 G, Qd		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

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Humira	S	Subcutaneous		Not Reported
Rituximab	S	Unknown		Not Reported
Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	1 G, Qd	Not Reported
Lyrica	C	Oral		Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Prednisone	C	Unknown	15 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13280419	EXPEDITED (15-DAY)	OT		CA-ROCHE-1681465			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 3 Years		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 10 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Therapy Duration: 21 Years		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 21 Years	Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13300820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1902134		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Parenteral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Azathioprine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Tofacitinib	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13303889	EXPEDITED (15-DAY)		OT	CA-ROCHE-1900072			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tylenol	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown	Not Reported
Apo-Acetaminophen	S	Unknown	Not Reported
Apo-Hydro	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Acetaminophen;Codeine Phosphate	C		Not Reported
Leflunomide	C	Unknown	Therapy Duration: 4 Months Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Celebrex	C		Not Reported
Hydromorphone Hcl	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13606666	EXPEDITED (15-DAY)		OT	CA-ROCHE-1941037			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown	Therapy Duration: 3 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months		Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Therapy Duration: 2 Years Single-Use Prefilled Syringe		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 730 Not Otherwise Specified		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 731 Not Otherwise Specified		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 5 Months		Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 1 Month		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 2 Months		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
Imuran [Azathioprine]	C		Not Reported
Vitamin D3	C	Unknown	Not Reported
Arthrotec	C	Unknown	Not Reported
Clindamycin	C		Not Reported
Cloxacillin	C		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
Ergocalciferol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13704329	EXPEDITED (15-DAY)		OT	CA-ROCHE-1955170			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Alopecia; Anxiety;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Arthralgia; Arthralgia;	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Asthenia; Contraindicated Product Administered;	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Depression; Diarrhoea;	Apo-Prednisone			S	Unknown			Not Reported
Drug Dependence; Drug Ineffective; Drug Use Disorder; Fall; Fatigue;	Enbrel			S	Subcutaneous			Not Reported
Headache; Inflammation;	Humira			S	Subcutaneous			Not Reported
Joint Injury; Liver Disorder; Malaise; Nausea; Pain;								
Red Blood Cell								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Dexamethasone	C		Not Reported
	Acetaminophen	C		Not Reported
	Gabapentin	C		Not Reported
	Reactine [Cetirizine Hydrochloride]	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13915547	EXPEDITED (15-DAY)		OT	CA-ROCHE-1982329		23 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	C	Oral	Therapy Duration: 365 Days	Not Reported
Hydroxychloroquine	C	Oral	Therapy Duration-365	Not Reported
Hydroxychloroquine	C	Oral		Not Reported
Hydroxychloroquine	C	Oral		Not Reported
Leflunomide	C	Oral	Therapy Duration: 549 Days	Not Reported
Orencia	C			Not Reported
Xeljanz	C	Oral		Not Reported
Folic Acid	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Tofacitinib Citrate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13948093	EXPEDITED (15-DAY)	OT		CA-ROCHE-1708212			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	4 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	13974176	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP017989			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S				Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S				Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Anakinra			S				Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Ilaris			S	Subcutaneous	Unk		Not Reported
	Ilaris			S	Unknown	Unk		Not Reported
	Methotrexate			S	Intra-arterial	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Orencia			S				Not Reported
Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Remicade			S	Unknown	Unk		Not Reported	
Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Rituxan			S	Unknown	Unk		Not Reported	
Sulfasalazine			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S			Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S			Not Reported
Gold	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14128207	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP020228		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; No Adverse Event; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14152209	EXPEDITED (15-DAY)		HO	CA-ROCHE-2013407			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fractures; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14235033	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2017AP021680		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	25 Mg, B.I.Wk.		Not Reported
	Enbrel			S	Unknown	25 Mg, Unk		Not Reported
	Humira			S	Unknown	40 Mg, Q.O.Wk.		Not Reported
	Methotrexate			S	Unknown	20 Mg, Q.Wk.,731.0		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Q.Wk.	Not Reported
Methotrexate	S	Unknown	15 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown		Not Reported
Remicade	S	Unknown	300 Mg, Once Every 6 Weeks	Not Reported
Remicade	S	Unknown	300 Mg, Once Every 6 Weeks	Not Reported
Rituxan	S	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14242686	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021958		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angina Pectoris;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
Arthralgia; Aspartate	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
Aminotransferase	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
Increased; Cardiac	Enbrel			S	Unknown			Not Reported
Murmur; Drug Intolerance;	Humira			S	Subcutaneous	Unk		Not Reported
Dyspnoea Exertional;	Methotrexate			S	Oral	20 Mg, Q.Wk.		Not Reported
Fatigue; Hyperkeratosis;	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
Interstitial Lung Disease;	Asa			C	Unknown	81 Mg, Unk		Not Reported
Joint Swelling;	Clonazepam			C	Oral	0.5 Mg, Unk		Not Reported
Osteoarthritis; Therapeutic	Desipramine			C	Unknown	50 Mg, Unk		Not Reported
Product Effect Decreased;	Gabapentin			C	Oral	300 Mg, Unk		Not Reported
Therapeutic Product Effect Decreased								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nitroglycerin	C	Unknown		Not Reported
Rosuvastatin Calcium	C	Oral	20 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14713133	EXPEDITED (15-DAY)	OT		CA-ROCHE-2095769		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringes Single-Use, Preservative-Free Prefilled Syringe; Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Gold			S	Intramuscular			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14801305	EXPEDITED (15-DAY)	OT		CA-ROCHE-2109842			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non-Responder; Tuberculin Test Positive	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Celecoxib	S	Oral	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Toradol	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Tramadol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	14849865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2114738		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	15322930	EXPEDITED (15-DAY)		DS	CA-ROCHE-2174731		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Prefilled Syringe; Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Not Specified		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	15342316	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178182		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	15449266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2191560		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Xeljanz			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17008473	EXPEDITED (15-DAY)		DS	CA-ROCHE-2454415			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthriti; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Indometacin			S	Oral			Not Reported	
	Indometacin			S	Oral			Not Reported	
	Indometacin			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Indomethacin [Indometacin]			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17023604	EXPEDITED (15-DAY)		DS	CA-ROCHE-2459894		64 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankle Operation; Arthralgia; Arthropathy; Asthenia; C-Reactive Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Celecoxib			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zoster; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17042231	EXPEDITED (15-DAY)		HO	CA-ROCHE-2465088		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17042658	EXPEDITED (15-DAY)	HO		CA-ROCHE-2465443		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
Folic Acid			C	Unknown			Not Reported	
Methotrexate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17233344	EXPEDITED (15-DAY)	OT		CA-ROCHE-2509589		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Supeudol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17240953	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019056593		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Pain; Therapeutic Product Effect Decreased	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S		50 Milligram		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram Solution		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Kevzara			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Tocilizumab			S		Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported
	Sarilumab			S				Not Reported
	Folic Acid			C				Not Reported
	Rabeprazole Sodium			C	Oral	20 Milligram, Once Daily (Qd)		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17259828	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514035		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Pain; Peripheral Swelling; Rash; Swelling; Tendon Operation; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Penicillin-G			S	Unknown			Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17412202	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA- 202002000692			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17578035	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP009106			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Folic Acid			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Cetirizine			S	Unknown	10 Mg, Unk		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Cortisone Acetate			S	Topical	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Fosamax			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported	
	Reactin /00884302/			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituxan			S	Intravenous (not	Unk		Not Reported	

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Simponi	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17580690	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-023759		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Intentional Product Use Issue; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	
	Leflunomide			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Xeljanz			S	Unknown	12.5 Milligram		Not Reported	
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17605620	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200333278		52 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Vaginal			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral	Cyclical		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Risedronate			S	Unknown			Not Reported
	Risedronate			S	Unknown			Not Reported
	Risedronate Sodium			S	Oral			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

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Xeljanz		S		otherwise specified) Oral		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17662281	EXPEDITED (15-DAY)			FR-ADVANSZ PHARMA- 202003002582			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17665011	NON-EXPEDITED			US-PFIZER INC- 2020152441		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Enbrel			S		Unk		Unknown	
	Methotrexate Sodium			S		Unk		Pfizer	
	Humira			S		Unk		Not Reported	
	Plaquenil			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17665283	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2017AP021759		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Hydroxychloroquine			S	Oral	2 Df, Qd		Apotex	
	Hydroxychloroquine			S	Oral	5 Mg, Bid		Apotex	
	Hydroxychloroquine			S	Oral	10 Mg, Qd		Apotex	
	Hydroxychloroquine			S	Subcutaneous	Unk		Apotex	
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Apotex	
	Apo-Hydroxyquine			S	Oral	Unk		Apotex	
	Apo-Leflunomide			S	Oral	Unk		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	

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Leflunomide	S	Oral	Unk	Apotex
Cyclosporine	S	Oral	Unk	Apotex
Cyclosporin	S	Subcutaneous	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S			Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.O.Wk.	Not Reported
Methotrexate	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Unk	Not Reported
Methotrexate Sodium	S	Oral	20 Mg, Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Rituximab	S	Endocervical	Unk	Not Reported
Rituximab	S			Not Reported

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Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S			Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	2 Df, Qd	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	Unk, Qd	Not Reported
Xeljanz	C	Oral	Unk	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz Xr	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17670925	EXPEDITED (15-DAY)		DE, OT	ES-CIPLA LTD.- 2020ES02594			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Levofloxacin			S	Unknown	Unk		Cipla
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Per Day		Not Reported
	Azitromicina			S	Oral	500 Milligram, Per Day		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid, (12 H)		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown	Unk		Not Reported
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Per Day		Not Reported
	Prednisona			C	Oral	20 Milligram, Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17671057	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP009843			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, B.I.Wk.	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Unk (Cyclical)	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Unk Cyclical	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, T.I.W	Apotex
	Hydroxychloroquine	S	Unknown	200 Mg, Q.O.Wk.	Apotex
	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Unknown	Unk	Apotex
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, B.I.Wk.	Not Reported
	Actemra	S	Subcutaneous	162 Mg, Q.O.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Adalimumab	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Prednisone	C	Unknown	20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17688373	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP016273		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Folic Acid			S	Unknown	Unk		Not Reported	
Alopecia; Anti-Cyclic	Prednisone			S	Unknown	Unk		Not Reported	
Citrullinated Peptide	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex	
Antibody Positive;	Hydroxychloroquine			S		Unk		Apotex	
Condition Aggravated;									

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Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Rash; Rheumatoid Factor Positive; Swelling; Systemic Lupus Erythematosus; Wound	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Cetirizine	S	Unknown	Unk	Apotex
	Methotrexate	S	Oral	25 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Reactine /00884302/	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Every One Day	Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Topicort /00028604/	S	Cutaneous	Unk	Not Reported
	Xeljanz	C	Unknown		Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17688732	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200411522		47 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Arthralgia; Back Pain;	Simponi	S	Subcutaneous	Janssen
Blood Pressure Increased;	Simponi	S	Subcutaneous	Janssen
Contraindicated Product	Remicade	S	Intravenous (not	Janssen
Administered; Drug			otherwise specified)	
Hypersensitivity; Drug	Actemra	S	Unknown	Not Reported
Ineffective; Drug	Arava	S	Unknown	Not Reported
Intolerance; Dyspnoea;	Cimzia	S	Subcutaneous	Not Reported
Gout; Infection; Joint	Enbrel	S	Unknown	Not Reported
Swelling; Liver Function	Gold	S	Unknown	Not Reported
Test Abnormal; Liver	Humira	S	Subcutaneous	Not Reported
Function Test Increased;	Methotrexate	S	Subcutaneous	Not Reported
Loss Of Personal	Methotrexate	S	Oral	Not Reported
Independence In Daily	Methotrexate	S	Oral	Not Reported
Activities; Metabolic	Orencia	S	Unknown	Not Reported
Surgery; Middle Insomnia;	Plaquenil /00072602/	S	Unknown	Not Reported
Migraine; Musculoskeletal	Rituxan	S	Intravenous (not	Not Reported
Pain; Musculoskeletal			otherwise specified)	
Stiffness; Nausea; Off	Sulfasalazine	S	Unknown	Not Reported
Label Use; Osteomyelitis;	Celebrex	S	Unknown	Not Reported
Pain In Extremity;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Peripheral Swelling;	Adalimumab	S	Subcutaneous	Not Reported
Product Use Issue;	Anakinra	S	Unknown	Not Reported
Rheumatoid Arthritis;	Leflunomide	S	Oral	Not Reported
Sensitivity To Weather	Leflunomide	S	Unknown	Not Reported
Change; Swelling;	Allopurinol	C	Unknown	Not Reported
Synovitis; Therapeutic	Clomipramine	C	Unknown	Not Reported
Product Effect Decreased;	Folic Acid	C	Unknown	Not Reported
Weight Increased	Pantoloc /01263201/	C	Unknown	Not Reported
	Zyloprim	C	Unknown	Not Reported
	Fentanyl	C	Unknown	Transdermal Patch

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Fentanyl Citrate			C	Unknown	Liquid Epidura			Not Reported	
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06-May-2020	17689640	EXPEDITED (15-DAY)		DE, HO, OT	SK-BAXTER-2020BAX007949		57 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral Infarction; Dizziness; Hypotension; Intentional Product Use Issue; Jc Virus Infection; Mental Impairment; Off Label Use; Pneumonia; Progressive Multifocal Leukoencephalopathy; Respiratory Failure; Speech Disorder; Tremor	Endoxan 1000 Mg Prasok Na Injekcny Roztok			S	Unknown	Unk		Baxter	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Cyclosporine A			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Belimumab			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17699793	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586666		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect	Actemra			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Incomplete; Treatment Failure	Orencia	S	Unknown	Not Reported
	Piroxicam	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Pregabalin	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Teva Mycophenolate	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17713157	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020161842		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dementia; Drug Ineffective; Pneumonia; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Hydroxychloroquine			S		200 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17715830	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245242		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg Dia		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17729805	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020171215		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer	
	Azithromycin			S				Pfizer	
	Dolquine			S	Other	400 Mg, Daily (Via Nasogastric Tube)		Not Reported	
	Dolquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17732183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590384		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Joint Swelling; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591079		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Cutaneous	Actemra			S	Intravenous (not otherwise specified)			Not Reported	

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Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Anakinra	S	Subcutaneous	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592025		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetic Eye Disease; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Hepatic Enzyme Increased; Rheumatoid Arthritis; Type 1 Diabetes Mellitus; Vomiting	Actemra			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748502	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-021696		43 YR	Female	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748521	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022017		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Dia		Aurobindo	
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram		Not Reported	
	Roactemra			S				Not Reported	
	Lopinavir;Ritonavir			S	Oral	2 U, Two Times A Day		Not Reported	
	Lopinavir;Ritonavir			S				Not Reported	
	Hidroxicloroquina			S	Oral	400 Milligram, Dia		Not Reported	
Hidroxicloroquina				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748548	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050103			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Qd		Zydus Pharm	
	Plaquenil Sulfate			S	Oral	800 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748701	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-022018		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Long Qt	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	

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Syndrome	Hydroxychloroquine	S	Oral	400 Milligram, Once A Day	Not Reported
	Hydroxychloroquine	S			Not Reported
	Roactemra	C	Intravenous (not otherwise specified)	600 Milligram,1 Total	Not Reported
	Roactemra	C			Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	2 Gram, Once A Day	Not Reported
		C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17748835	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591229		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593194			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Contraindicated Product Administered; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749117	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592495			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592694		50 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Supeudol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749294	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593188			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749417	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591882			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592483		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Back Disorder; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Mouth	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported

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Ulceration; Vasculitic Rash	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593219			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Pain	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749626	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590880			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Rheumatoid	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

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Arthritis; Systemic Lupus Erythematosus	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749765	EXPEDITED (15-DAY)		OT	NVSC2020IR111437		24 YR	Female	IRN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Osteonecrosis	Prednisolone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749788	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1230789		51 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia	Hidroxiclороquina (2143a)			S	Oral	800 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749846	EXPEDITED (15-DAY)		HO, OT	US-ADVANZ PHARMA-202004004835			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Hydroxychloroquine			S		7 Little Pills		Concordia	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17749889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590257		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Ciprofloxacin			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Tridural			C	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine			C				Not Reported	

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Sulfate] Tylenol		C		Not Reported					
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06-May-2020	17750016	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2590470		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; C-Reactive Protein	Actemra			S	Unknown			Not Reported	
Abnormal; Contraindicated	Actemra			S	Unknown			Not Reported	
Product Administered; Deep Vein Thrombosis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
Diverticulitis; Drug Ineffective; Intentional	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
Product Use Issue; Joint Arthroplasty; Joint Swelling; Knee	Anakinra			S	Unknown			Not Reported	
Arthroplasty; Myocardial Infarction; Off Label Use;	Anakinra			S				Not Reported	
Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal	Apo-Leflunomide			S	Unknown			Not Reported	
Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Apo-Leflunomide			S				Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cannabis Sativa			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Gold			S				Not Reported	
	Humira			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Ilaris			S	Unknown			Not Reported	

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Ilaris	S	Subcutaneous	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Minocycline	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750116	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1230679		70 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Bundle Branch Block Right; Hypertension;	Hidroxyclozoquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
Hypofibrinogenaemia; Pneumonia Escherichia;	Hidroxyclozoquina (2143a)			S				Teva	
Ventricular Tachycardia	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	

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		Tocilizumab (8289a)		S	Intravenous (not otherwise specified)	600 Mg			Not Reported
		Tocilizumab (8289a)		S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750118	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230310		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750156	EXPEDITED (15-DAY)		HO	SE-ACCORD-180870		16 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Fatigue; Intentional Overdose; Intentional Self-Injury; Somnolence; Tachycardia	Sertraline			S	Oral	Intentional Overdose		Accord	
	Prednisolone			S	Oral	10-15 St, Intentional Overdose		Not Reported	
	Plaquenil			S	Oral	10-15 St, Intentional Overdose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750216	NON-EXPEDITED			US-PFIZER INC-2020180158		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Joint Swelling; Peripheral Swelling	Sulfasalazine			S		Unk		Pfizer	
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Plaquenil			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	

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06-May-2020	17750441	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-245841		51 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Glomerulonephritis Membranous	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun	
	Prednisolone			C	Unknown	Unk (40 Mg/ Day Of Prednisolone With Gradual Taper To 5 Mg/Day And Maintained)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750591	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592747		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown	94.0 Days		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Methotrexate			C	Oral			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750608	DIRECT	Y				53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immunodeficiency; Vomiting	Hydroxychloriquine		Y	S				Unknown	

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06-May-2020	17750700	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231666		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome	Codeine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram Daily;		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592032			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Actemra			S	Subcutaneous			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	

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Sarilumab	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sulfasalazine	S	Unknown	Not Reported

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06-May-2020	17750721	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-246167		73 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun
	Ertapenem (2881a)			S	Intravenous (not otherwise specified)	1 G Dia		Not Reported
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg,...			S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593603			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported

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	Enbrel	S	Unknown	Not Reported
	Sulfasalazine	C		Not Reported
	Wellbutrin	C		Not Reported
	Xeljanz	C		Not Reported

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06-May-2020	17750989	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1231349		72 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Doxycycline			S	Oral			Actavis	
	Azithromycin			S	Oral			Unknown	
	Amoxicillin And Clavulanate			S	Intravenous drip			Teva	
	Potassium Plaquenil			S	Oral	800 Mg 22-23/03, 400 Mg 24-26/03, 600 Mg 26- 30/03		Not Reported	
	Enoxaparin			S	Subcutaneous			Not Reported	
	Durogesic			S	Transdermal	Patch 25 Mcg/H : 1 Every 3 Days		Not Reported	

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06-May-2020	17751018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231681			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Constipation; Drug Hypersensitivity; Drug Ineffective; Rash; Rheumatoid Arthritis	Codeine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Barr	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Arava			C	Unknown	20 Milligram Daily;		Not Reported	
	Prednisone			C	Unknown			Not Reported	

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06-May-2020	17751040	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591815		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751253	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591867		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Prednisone			C	Unknown			Not Reported	

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Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

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06-May-2020	17751361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231392			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Test Abnormal; Inflammation; Local Reaction; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Syncope; Vomiting	Morphine Sulfate			S	Unknown			Actavis
	Codeine			S	Unknown			Not Reported
	Aclasta			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plantago Afra			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Asa			C	Unknown	81 Milligram Daily;		Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cannabis Sativa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown	2000 Iu (International Unit) Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lipitor			C	Unknown	10 Milligram Daily;		Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751521	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231640		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Rosuvastatin			S	Unknown			Teva

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Bone Erosion; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Erythema; Ill-Defined Disorder; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Actemra Arava Enbrel Gold Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Methotrexate Orencia Remicade Xeljanz	S S S S S S S S S C	Unknown Unknown Subcutaneous Unknown Unknown Unknown Oral Unknown Intravenous (not otherwise specified) Oral	10 Milligram Daily;	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751548	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020178177		45 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751585	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020180060		55 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Condition Aggravated; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephine			S	Oral	2 G, 1x/Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751680	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006814		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Apo-Leflunomide			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Apo-Leflunomide			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Apotex
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Oral	20 Mg, Unk		Apotex
	Cyclosporine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Cyclosporine			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.O.Wk.		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	75 Mg, Q.M.T.		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not	Unk		Not Reported

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			otherwise specified)		
Rituximab	S	Endocervical	Unk		Not Reported
Neoral	S	Oral	Unk		Not Reported
Neoral	S	Subcutaneous	Unk		Not Reported
Neoral	S	Oral	Unk		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg, Unk		Not Reported
Methotrexate Sodium	S	Unknown	Unk		Not Reported
Methotrexate	S	Oral	20 Mg, Unk		Not Reported
Methotrexate	S	Subcutaneous	25 Mg, Q.Wk.		Not Reported
Methotrexate	S	Subcutaneous	20 Mg, Unk		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg, Unk		Not Reported
Xeljanz	S	Oral	5 Mg, Bid		Not Reported
Xeljanz	S	Unknown	2 Df, Qd		Not Reported
Simponi	S	Subcutaneous	Unk		Not Reported
Arava	C	Oral	20 Mg, Qd		Not Reported
Plaquenil /00072602/	C	Unknown	Unk		Not Reported
Risedronate	C	Oral	35 Mg, Q.Wk.		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Unk		Not Reported
Rituxan	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported
Xeljanz Xr	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751718	EXPEDITED (15-DAY)		OT	NVSC2020FR120436		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Lamprene			S	Oral	100 Mg, Qd		Novartis

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Plaquenil	S	Oral	1 Df, Qd	Not Reported
Noxafil	S	Oral	300 Mg, Qd	Not Reported
Zithromax	S	Oral	250 Mg, Qd	Not Reported
Ursodesoxycholic Acid	C	Unknown	Unk	Not Reported
Propranolol	C	Unknown	Unk	Not Reported
Ethambutol	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Tramadol	C	Unknown	Unk	Not Reported
Aldactone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751868	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2020178146		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Embolism	Amlor			S	Oral	1 Df, 1x/Day		Pfizer
	Augmentin [Amoxicillin Trihydrate;Clavulanate Potassium]			S	Intravenous (not otherwise specified)	3 G, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Colchimax [Colchicine;Papaver Somniferum Powder;Tiemonium Methylsulpha			S	Oral	1 Df, 1x/Day		Not Reported
	Paracetamol			S	Oral	4 G, 1x/Day		Not Reported
	Arimidex			S	Oral	1 Mg, 1x/Day		Not Reported
	Nefopam Hydrochloride			S	Oral	80 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751882	EXPEDITED (15-DAY)	HO, OT		ES-PFIZER INC-2020178687		73 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Haemorrhage; Hepatitis	Azithromycin			S	Oral	500 Mg, Daily		Pfizer

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Acute; Off Label Use; Product Use In Unapproved Indication	Ertapenem	S	Intravenous (not otherwise specified)	1 G, Daily	Not Reported
	Piperacillin/Tazobactam	S	Intravenous (not otherwise specified)	C/24h	Not Reported
	Dolquine	S	Oral	400 Mg, Daily	Not Reported
	Dolquine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17751896	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020178145		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752072	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS- 050251			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram		Zydus Pharm
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Milligram		Not Reported
	Rocephin			S	Oral	2 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752139	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020178148		60 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported

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Product Use In Sulfate]
Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752148	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA119135			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Phenylephrine			S	Unknown	Unk		Novartis
Abnormal; Condition	Benzalkonium Chloride			S	Unknown	Unk		Not Reported
Aggravated; Drug	Diphenhydramine Hydrochloride		Y	S	Unknown	Unk		Not Reported
Hypersensitivity; Drug	Phenylephrine Hydrochloride			S	Unknown	Unk		Novartis
Ineffective; Drug	Sulfasalazine			S	Oral	Unk		Not Reported
Intolerance;	Rituximab			S	Unknown	Unk		Not Reported
Gastrointestinal Toxicity; Hepatotoxicity; Infection;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Not Reported
Joint Injury; Joint Swelling;	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
Musculoskeletal Pain;	Methotrexate			S	Subcutaneous	Unk		Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine			S	Unknown	Unk		Not Reported
Neoplasm Malignant; Pain	Boric Acid			S	Unknown	Unk		Not Reported
In Extremity; Pulmonary	Cimzia			S	Subcutaneous	Unk		Not Reported
Toxicity; Therapeutic	Disodium Edetate			S	Unknown	Unk		Not Reported
Product Effect Incomplete;	Enbrel			S	Subcutaneous	40 Mg, Qw		Not Reported
Therapy Non-Responder;	Gold			S	Unknown	Unk		Not Reported
Treatment Failure	Humira			S	Subcutaneous	40 Mg		Not Reported
	Arava			S	Unknown	20 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Qmo		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rho D Immune Globulin			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sodium Borate			S	Unknown	Unk		Not Reported

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Tofacitinib Citrate	S	Unknown	10 Mg, Q2w	Not Reported
Tofacitinib Citrate	S	Unknown	10 Mg, Q2w	Not Reported
Tofacitinib Citrate	S	Subcutaneous	10 Mg, Q2w	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Lipitor	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752280	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592856			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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	Xeljanz			C					Not Reported
	Prednisone			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592876		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Hepatitis; Therapeutic Product Effect Decreased	Actemra			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	
	Leflunomide			C	Unknown			Not Reported	
	Methotrexate			C	Subcutaneous			Not Reported	
	Methotrexate			C	Subcutaneous			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752382	EXPEDITED (15-DAY)		OT	US-AMNEAL PHARMACEUTICALS-2020-AMRX-01266		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Astigmatism; Cornea Verticillata	Hydroxychloroquine Sulfate			S	Unknown	600 Milligram, Bid		Amneal	

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Everolimus		C		Unknown		(1200mg, 21.9 Mg/Kg/Day) 10 Milligram, Qd	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752490	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK103006		31 YR	Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Growth Restriction; Maternal Exposure During Pregnancy; No Adverse Event; Oligohydramnios; Premature Baby	Cefotaxime			S	Unknown	Unk		Not Reported	
	Cefotaxime			S	Unknown	Unk		Not Reported	
	Bisoprolol Fumarate			S	Unknown	Unk		Novartis	
	Omeprazole			S	Unknown	Unk		Not Reported	
	Dexamethasone			S	Unknown	Unk		Not Reported	
	Dexamethasone			S	Unknown	Unk		Not Reported	
	Metoprolol Tartrate			S	Unknown	Unk		Not Reported	
	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported	
	Calcium Carbonate			S	Unknown	Unk		Not Reported	
	Cefixime			S	Unknown	Unk		Not Reported	
	Fluconazole			S	Unknown	Unk		Not Reported	
	Penicillin G Benzathine			S	Unknown	Unk		Not Reported	
	Vitamin K Nos			S	Unknown	Unk		Not Reported	
	Bisulepin			S	Unknown	Unk		Not Reported	
	Nadroparin Calcium			S	Unknown	Unk		Not Reported	
	Etamsylate			S	Unknown	Unk		Not Reported	
	Privigen			S	Unknown	Unk		Not Reported	
	Flebogamma Dif			S	Unknown	Unk		Not Reported	
	Potassium Chloride			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Vitamin B Complex			S	Unknown	Unk		Not Reported	

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Albumin	S	Unknown	Unk	Not Reported
Ornidazole	S	Unknown	Unk	Not Reported
Magnesium Lactate	S	Unknown	Unk	Not Reported
Methylprednisolone	S	Unknown	Unk	Not Reported
Methylprednisolone	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Amcal Hydrocortisone	S	Unknown	Unk	Not Reported
Vulmizolin	S	Unknown	Unk	Not Reported
Aminomethylbenzoic Acid	S	Unknown	Unk	Not Reported
Cc Vital Vitamin D [Cholecalciferol]	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752802	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1045203		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S		Unk		Not Reported	
	Plaquenil /00072602/			S		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752805	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045208		28 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Azithromycin			S				Not Reported	
	Dolquine			S	Oral	400 Mg Dia		Mylan	
	Dolquine			S				Mylan	
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan	

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Ceftriaxona /00672201/
Paracetamol

S
S

Intravenous (not
otherwise specified) 1gr Cada 8 Horas

Mylan
Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752820	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045211		63 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752855	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1045224		95 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Sudden Death	Quetiapine			S	Oral	25 Milligram, Qd		Not Reported
	Risperidone			S	Oral	1 Milligram, Qd		Not Reported
	Kaletra			S	Oral	2 Dosage Form, Qd		Mylan
	Hidroxiclороquina Sulfato			S	Oral	200 Milligram, Bid		Mylan
	Levofloxacin /01278901/			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan
	Furosemida /00032601/			C	Oral	40 Milligram, Qd		Mylan
	Losartan			C	Oral	50 Milligram, Qd		Mylan
	Clindamicina /00166002/			C	Intravenous (not otherwise specified)	600 Milligram, Q6h		Mylan
	Lorazepam			C	Oral	1 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752857	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1045184		70 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Not Reported	
	Plaquenil /00072603/			S	Oral	Unk		Mylan	
	Lovenox			C	Oral	Unk		Mylan	
	Paracetamol			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17752859	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045179		63 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Azithromycin			S				Not Reported	
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)	Cada 8 Horas		Not Reported	
	Amoxicillin/Clavulanic Acid			S				Not Reported	
	Dolquine			S	Oral	400 Mg Dia		Mylan	
	Dolquine			S				Mylan	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg Dia		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17753230	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592884		76 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown	365.0		Not Reported	
	Hydroxychloroquine			S	Unknown	5.0 Years		Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown	8.0 Years		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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06-May-2020	17753640	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-02		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Mobicox			S	Unknown			Boehringer Ingelheim	
Arthralgia; Conjunctivitis;	Xeljanz			S	Oral			Not Reported	
Drug Ineffective;	Xeljanz			S	Oral			Not Reported	
Dyspnoea; Erythema;	Vimovo			S	Unknown	Tablet (Delayed And Immediate Release)		Not Reported	
Haemoglobin Decreased;	Oxycocet			S	Unknown			Not Reported	
Infection; Joint Swelling;	Sulfasalazine			S	Oral			Not Reported	
Musculoskeletal Pain;	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported	
Nausea; Pain; Peripheral Swelling; Pneumonia;	Septra			S	Unknown			Not Reported	
Pruritus; Rash;	Ratio-Oxycocet			S	Unknown			Not Reported	
Rheumatoid Arthritis	Prednisone			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported	
	Methylprednisolone Sodium Succinate			S	Unknown			Not Reported	
	Oxycodone And Acetaminophen			S	Unknown			Not Reported	
	Naproxen			S	Unknown	Tablet (Enteric-Coated)		Not Reported	
	Naproxen			S	Oral	Tablet (Enteric-Coated)		Not Reported	
	Methotrexate			S	Subcutaneous	Solution		Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Imuran [Azathioprine]			S	Unknown			Not Reported	
	Humira (Adalimumab)			S	Subcutaneous			Not Reported	
	Esomeprazole			S	Unknown			Not Reported	
	Esomeprazole Magnesium			S	Unknown			Not Reported	

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Trihydrate;Naproxen	S	Subcutaneous		Not Reported
Enbrel	S	Oral	Elavil Pamoate Syr 10mg/5ml	Not Reported
Elavil [Amitriptyline Pamoate]	S	Intra-articular	Suspension Intra-Articular	Not Reported
Depo-Medrol	S	Unknown		Not Reported
Bactrim	S	Unknown		Not Reported
Apo-Ranitidine	S	Oral		Not Reported
Apo-Ranitidine	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Meloxicam	S	Unknown		Not Reported
Apo-Amitriptyline	S	Unknown		Not Reported
Apo-Alendronate	S	Unknown		Not Reported
Apo Naproxen	S	Unknown	Tablet (Entericcoated)	Not Reported
Apo Naproxen	S	Unknown	Tablet (Entericcoated)	Not Reported
Apo Naproxen	S	Oral	Tablet (Entericcoated)	Not Reported
Amitriptyline	S	Oral		Not Reported
Alendronate	S	Unknown		Not Reported
Pantoloc [Pantoprazole]	S	Oral	Tablet (Entericcoated)	Not Reported
Celebrex	C	Unknown		Not Reported
Celecoxib	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Hydroxychloroquine Sulfate	C	Unknown		Not Reported

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06-May-2020	17754146	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012923		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported

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Minocycline Hydrochloride	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Amoxicillin Sodium;Clavulanate Potassium Amoxil	C	Unknown	Not Reported
Bacillus Calmette-Guerin Bcg	C	Intravenous (not otherwise specified)	Not Reported
Bacillus Calmette-Guerin Bcg	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754149	EXPEDITED (15-DAY)		LT	CA-BAUSCH-BL-2020-012932		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Apparent Death;	Minocycline Hydrochloride	S	Unknown	Not Reported
Arthropathy; C-Reactive	Minocycline	S	Unknown	Not Reported
Protein Abnormal; C-	Actemra	S	Unknown	Not Reported
Reactive Protein	Actemra	S		Not Reported
Increased;	Anakinra	S	Unknown	Not Reported
Contraindicated Product	Anakinra	S		Not Reported
Administered; Deep Vein	Anakinra	S		Not Reported
Thrombosis; Diverticulitis;	Arava	S	Unknown	Not Reported
Drug Hypersensitivity;	Arava	S		Not Reported
Drug Ineffective; Drug	Enbrel	S	Subcutaneous	Not Reported
Intolerance; Feeling	Enbrel	S		Not Reported
Abnormal; Haemoglobin	Gold	S	Unknown	Not Reported
Decreased; Herpes	Humira	S	Subcutaneous	Not Reported
Zoster; Intentional Product	Humira	S	Unknown	Not Reported
Use Issue; Interstitial Lung	Hydroxychloroquine	S	Unknown	Not Reported
Disease; Joint Swelling;	Hydroxychloroquine	S		Not Reported
Myocardial Infarction; Off	Ilaris	S	Subcutaneous	Not Reported
Label Use; Pain;	Ilaris	S		Not Reported
Photosensitivity Reaction;	Leflunomide	S	Unknown	Not Reported
Pulmonary Embolism;	Leflunomide	S		Not Reported
Pulmonary Thrombosis;	Marijuana	S	Unknown	Not Reported
Red Blood Cell	Methotrexate	S	Unknown	Not Reported
Sedimentation Rate	Methotrexate	S		Not Reported
Increased; Renal Failure;	Methotrexate Sodium	S	Unknown	Not Reported
Sepsis; Stomatitis;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Terminal State;	Orencia	S		Not Reported
Thrombosis; Urticaria	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported

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Rituximab	S			Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral		Not Reported
Kineret	C			Not Reported
Lyrica	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754163	EXPEDITED (15-DAY)		DE, LT	CA-BAUSCH-BL-2020-012936		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Minocycline Hydrochloride			S	Unknown			Not Reported
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Minocycline			S	Unknown			Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Actemra			S	Unknown	Dosage Form Not Specified		Not Reported
Drug Hypersensitivity;	Actemra			S				Not Reported
Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling;	Anakinra			S	Unknown			Not Reported
Myocardial Infarction; Off Label Use; Pain;	Anakinra			S				Not Reported
Photosensitivity Reaction;	Arava			S	Unknown			Not Reported
Pulmonary Embolism;	Arava			S				Not Reported
Pulmonary Thrombosis;	Enbrel			S	Subcutaneous			Not Reported
Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Enbrel			S				Not Reported
Sepsis; Stomatitis;	Gold			S	Unknown			Not Reported
	Gold			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Subcutaneous			Not Reported

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Terminal State; Thrombosis; Urticaria	Leflunomida	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Kineret	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754170	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-012998		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol (2297a)			S	Respiratory (inhalation)			Bausch And Lomb	

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Dolquine	S	Oral	30 Tablets	Not Reported
Metoclopramida (1958a)	S	Intravenous (not otherwise specified)		Not Reported
Propofol (2373a)	S	Intravenous (not otherwise specified)		Not Reported
Azitromicina (7019a)	S	Oral		Not Reported
Ipratropio Bromuro (1067br)	C	Respiratory (inhalation)		Not Reported
Cefotaxima (3840a)	C	Intravenous drip		Not Reported
Midazolam (2256a)	C	Intravenous drip		Not Reported
Enoxaparina Sodica (2482so)	C	Subcutaneous		Not Reported
Tocilizumab (8289a)	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754176	EXPEDITED (15-DAY)		HO, LT	CA-BAUSCH-BL-2020-012937			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein Increased;	Minocycline Hydrochloride			S	Unknown			Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Minocycline			S	Unknown			Not Reported
Drug Hypersensitivity;	Xeljanz			S	Oral			Not Reported
Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Sulfasalazine			S	Unknown			Not Reported
Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use;	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S				Not Reported
	Plaquenil			S	Oral			Not Reported

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Pain; Photosensitivity	Plaquenil	S		Not Reported
Reaction; Pulmonary	Oxycodone	S	Unknown	Not Reported
Embolism; Red Blood Cell	Orencia	S	Intravenous (not	Not Reported
Sedimentation Rate			otherwise specified)	
Increased; Renal Failure;	Orencia	S		Not Reported
Sepsis; Stent Placement;	Methotrexate Sodium	S	Unknown	Not Reported
Stomatitis; Thrombosis;	Methotrexate Sodium	S		Not Reported
Urticaria	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Actemra	S		Not Reported

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06-May-2020	17754228	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180840374			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Urticaria; Wrist Surgery	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754231	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180836875		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
Dorzolamide Hydrochloride/Timolol Maleate	S	Ophthalmic	Not Reported
Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Levothyroxine Sodium	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Ramipril	S	Oral	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Cosopt	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Codeine Phosphate W/Paracetamol	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Tylenol 2	C	Unknown	Not Reported
Acetaminophen W/Caffeine	C	Unknown	Not Reported
Plaquenil	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C		Not Reported
Caffeine	C		Not Reported
Hydroxychloroquine Phosphate	C		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754512	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230680		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1gr Every 8 Hours		Not Reported
	Metamizol (111a)			S	Intravenous (not otherwise specified)	2gr Every 6 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754585	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3387973-00		51 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Hepatocellular Injury; Liver Function Test Increased; Off Label Use; Off Label Use	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Augmentin			S	Intravenous drip			Not Reported
	Plaquenil			S	Oral			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Clexane			S	Subcutaneous			Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)	Maximum 3 Times A Day		Not Reported
	Piperacilline/Tazobactam			S	Intravenous drip			Not Reported
	Zithromax			S	Oral			Not Reported
	Ipramol			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Temesta	C	Not Reported
Tavanic	C	Not Reported
Atracurium	C	Not Reported
Fentanyl	C	Not Reported
Dormicum	C	Not Reported
Phosphate	C	Not Reported
Colistin	C	Not Reported
Torasemide	C	Not Reported
Potassium Chloride	C	Not Reported
Benerva	C	Not Reported
Heparin	C	Not Reported
Solu-Medrol	C	Not Reported
Relistor	C	Not Reported
Novasource Gi Control	C	Not Reported
Ventolin	C	Not Reported
Movicol	C	Not Reported
Novorapid	C	Not Reported
Tobramycin	C	Not Reported
Amphotericin B	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594253		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594194		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	11105334	EXPEDITED (15-DAY)		OT	CA-ROCHE-1574386			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C- Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral;	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Subcutaneous	Duration : 1095 Days		Not Reported	
	Enbrel			S	Unknown	Unknown		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use Issue;	Xeljanz	S	Unknown	Not Reported
Rheumatoid Arthritis; Soft	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported
Tissue Swelling;	Sulfate]			
Stomatitis; Swelling;	Humira	S	Subcutaneous	Not Reported
Synovitis; Tenderness;	Humira	S	Subcutaneous	Not Reported
Therapeutic Product Effect	Humira	S	Unknown	Not Reported
Incomplete	Humira	S	Solution For Injection	Not Reported
	Remicade	S	Intravenous (not	Not Reported
			otherwise specified)	
	Remicade	S	Intravenous (not	Not Reported
			otherwise specified)	
	Remicade	S	Intravenous (not	Not Reported
			otherwise specified)	
	Remicade	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Orencia	S	Intravenous (not	Not Reported
			otherwise specified)	
	Methotrexate Sodium	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Benadryl [Diphenhydramine	C		Not Reported
	Hydrochloride]			
	Synthroid	C		Not Reported
	Lasix [Furosemide]	C	Unknown	Not Reported
	Enablex [Darifenacin	C		Not Reported
	Hydrobromide]			
	Ativan	C		Not Reported
	Loperamide	C	Unknown	Not Reported
	Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
	Omnaris	C	Unknown	Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vagifem	C	Vaginal	Not Reported
Cortisone	C	Intramuscular	Not Reported
Dilaudid	C	Unknown	Not Reported
Abatacept	C		Not Reported
Leflunomide	C		Not Reported
Kineret	C		Not Reported
Furosemide	C	Unknown	Not Reported
Diphenhydramine Hydrochloride	C		Not Reported
Darifenacin Hydrobromide	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Oxyneo	C	Unknown	Not Reported
Trimethoprim	C		Not Reported
Restasis	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C		Not Reported
Kadian	C	Unknown	Not Reported
Codeine	C		Not Reported
Acetaminophen	C		Not Reported
Anakinra	C		Not Reported
Desoximetasone	C		Not Reported
Dexamethasone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	12098241	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712937			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy;	Actemra			S	Unknown			Not Reported
Carpal Tunnel Syndrome;	Methotrexate Sodium			S	Unknown	Dose Reduced		Not Reported
Condition Aggravated;	Methotrexate Sodium			S	Unknown			Not Reported
Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown			Not Reported
Intolerance; Gait	Prednisone			S	Unknown			Not Reported
Disturbance; Hip Fracture;	Leflunomide			S	Unknown	Frequency: Every 1 Day;		Not Reported
Intervertebral Disc						Therapy Duration: 4		
Disorder; Mobility						Months, Stopped Due To		
Decreased;						Nausea,Vomiting,		
Musculoskeletal								
Discomfort; Nausea; Pain;								
Rheumatoid Arthritis;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Stress Fracture; Vomiting; Wrist Deformity	Enbrel	S	Unknown	Intolerance	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	12810481	EXPEDITED (15-DAY)		OT	CA-ROCHE-1837479		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Joint Swelling; Pain; Pain	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Tylenol			C	Unknown	As Required		Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	12881921	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013278		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug	Apo-Hydroxyquine			S	Unknown	400 Mg, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Apo-Leflunomide	S	Unknown	Unk	Apotex
	Naproxen Sodium Tablets	S	Unknown	Unk	Not Reported
	Naproxen	S	Unknown	Unk	Apotex
	Hydroxychloroquine	S	Unknown	400 Mg, Unk	Apotex
	Hydroxychloroquine	S			Apotex
	Prednisone	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S			Apotex
	Naproxen Sodium	S	Unknown	Unk	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	12.5 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Prednisone Acetate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulphate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Subcutaneous	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Naproxen	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	20 Mg, Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	12891035	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013489			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40mg/0.8ml		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zostavax			S	Subcutaneous	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	
	Xeljanz			C	Oral	10 Mg, Bid		Not Reported	
	Cortisone /00014602/			C	Unknown	Unk		Not Reported	
	Diclofenac /00372302/			C	Subcutaneous	100 Mg, Unk		Not Reported	
	Cortisone Acetate			C	Subcutaneous	Unk		Not Reported	
	Desoximetasone			C	Oral	Unk		Not Reported	
	Desoximetasone			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	12923504	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1632295			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Pre-Filled Syringe		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
Apo-Hydroxyquine			S	Unknown			Not Reported	

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Sodium Aurothiomalate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Methotrexate	C		Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	12981186	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853913			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Nausea; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Cimzia			S	Subcutaneous	Single Use, Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Diclofenac Sodium/Misoprostol	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Arthrotec	C	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Therapy Duration: 8 Years	Not Reported
	Imuran [Azathioprine]	C	Unknown		Not Reported
	Vitamin D3	C	Oral		Not Reported
	Azathioprine	C			Not Reported
	Ergocalciferol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13099777	EXPEDITED (15-DAY)		OT	CA-ROCHE-1595142		43 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated;	Rituxan			S	Intravenous (not otherwise specified)	Cyclical, Therapy Duration: 8 Months		Not Reported
Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Drug Ineffective; Impaired Work Ability; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain;	Methotrexate Sodium			S	Subcutaneous	Went Up To 25 Mg		Not Reported
Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Did Not Work Therapy Duration: 3 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 3 Years	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Sodium Aurothiomalate	S	Intramuscular		Not Reported
Actonel	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13099811	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876558			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bronchitis; Bronchospasm; Contraindicated Product Administered; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Mirtazapine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Lyrice			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13103523	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876554		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated;	Actemra	S	Subcutaneous	Not Reported
Contraindicated Product	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Administered; Drug				
Hypersensitivity; Drug	Cellcept [Mycophenolate Mofetil]	S	Unknown	Not Reported
Ineffective; Drug	Enbrel	S	Subcutaneous	Not Reported
Intolerance; Joint Swelling;	Methotrexate Sodium	S	Unknown	Not Reported
Multiple Allergies;	Methotrexate Sodium	S	Subcutaneous	Not Reported
Musculoskeletal Pain; Off	Methotrexate Sodium	S	Intra-arterial	Not Reported
Label Use; Pain; Product	Sulfasalazine	S	Unknown	Not Reported
Use In Unapproved	Arava	S	Oral	Not Reported
Indication; Psoriatic	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Arthropathy; Rash; Red	Remicade	S	Unknown	Not Reported
Blood Cell Sedimentation	Orencia	S	Unknown	Not Reported
Rate Increased;	Simponi	S	Unknown	Not Reported
Rheumatic Disorder;	Humira	S	Unknown	Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown	Not Reported
Sciatica; Sinusitis;	Lyrica	S	Oral	Not Reported
Swelling; Therapeutic	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
Product Effect Incomplete;	Apo Mycophenolate	S	Unknown	Not Reported
Therapeutic Product Effect	Mycophenolate	S	Unknown	Not Reported
Incomplete; Treatment	Apo-Hydroxyquine	S	Unknown	Not Reported
Failure	Methotrexate	S	Unknown	Not Reported
	Cimzia	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Leflunomide	C		Not Reported
	Morphine	C		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13116927	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878962		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Desoximetason			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13136489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1882213		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Drug Ineffective; Joint Injury; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Pain; Pain In Extremity; Peripheral Swelling; Swelling	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13233237	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893773		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Injury; Joint Swelling; Pain; Peripheral Swelling; Retinal Toxicity; Swelling	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13251590	EXPEDITED (15-DAY)		CA, OT	CA-APOTEX-2017AP006777		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased;	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Apo-Leflunomide			S	Unknown	10 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	22.5 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	25 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Oral	25 Mg, Qd	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Bid	Not Reported
	Prednisone	C	Oral	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13315469	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808080		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cortisone			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown	1/2 Tablet As Needed		Not Reported
	Tylenol			C	Unknown	As Needed		Not Reported

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Prednisone Acetate	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13735259	EXPEDITED (15-DAY)		HO, LT, OT	CA-ROCHE-1356654		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Creatinine Increased; Blood Pressure Decreased; Blood Pressure Fluctuation; Blood Pressure Increased; Body Temperature Decreased; Cataract; Chills; Colitis Microscopic; Cough; Diarrhoea; Ear Pruritus; Fatigue; Headache; Hypertension; Hypotension; Hypotension; Hypotension; Malaise; Nasal Congestion; Nasopharyngitis; Nasopharyngitis; Oral Pruritus; Perforated Ulcer; Procedural Pain; Pyrexia; Renal Disorder; Single Functional Kidney; Sleep Disorder; Throat Irritation; Weight Decreased; Weight Increased; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)	Form Strength: 500 Mg/50 MI Most Recent Dose Was On 19/Jun/2014 Most Recent Rituxan Dose On 18/Jan/2		Not Reported
	Naproxen			S	Unknown			Not Reported
	Apo-Leffunomide			S	Unknown	Stopped Approx. Aug 2013		Not Reported
	Prednisone			S	Unknown	Stopped Approx. Jan 2013		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Diphenhydramine Hcl			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			C				Not Reported
	Pms-Sulfasalazine			C				Not Reported
	Eltroxin			C				Not Reported
	Gabapentin			C				Not Reported
	Hydromorphone			C				Not Reported
	Lansoprazole			C				Not Reported
	Lorazepam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13952660	EXPEDITED (15-DAY)		OT	CA-ROCHE-1990184		53 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Fatigue; Groin Pain; Joint Noise; Joint Range Of Motion Decreased; Joint Stiffness; Middle Insomnia; Nonspecific Reaction; Pain In Extremity; Peripheral Swelling; Retinal Toxicity	Actemra			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	13957945	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017756		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Platelet Count Decreased; Sinusitis; Sleep Disorder; Tendon Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Orencia			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			S	Unknown	200 Mg, Qd		Not Reported	
	Xeljanz			S	Oral	5 Mg, Qd		Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
	Advil /00044201/			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	Ketorolac			C	Unknown	Unk		Not Reported	
	Naproxen			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported	

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Methotrexate			C	Unknown	20 Mg, Q.Wk.	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	14238407	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2017AP021637		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex	
Ankle Fracture; Anti-Cyclic	Leflunomide			S	Unknown	20 Mg, Unk		Apotex	
Citrullinated Peptide	Indomethacin			S	Unknown	Unk		Not Reported	
Antibody Positive;	Prednisone			S	Oral	25 Mg, Qd		Apotex	
Arthralgia; Asthenia; Back	Prednisone			S	Oral	3 Mg, Qd		Apotex	
Pain; Bone Density	Prednisone			S	Oral	50 Mg, Unk		Apotex	
Abnormal; Contraindicated	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
Product Administered;	Apo-Prednisone			S	Oral	3 Mg, Qd		Apotex	
Crying; Decreased	Apo-Prednisone			S	Oral	50 Mg, Qd		Apotex	
Appetite; Depression;	Enbrel			S	Unknown	Unk		Not Reported	
Disability; Drug Ineffective;	Enbrel			S	Subcutaneous	Unk		Not Reported	
Fatigue; Headache;	Humira			S	Subcutaneous	Unk		Not Reported	
Hypercholesterolaemia;	Methotrexate Sodium			S	Oral	Unk		Not Reported	
Infection; Joint Stiffness;	Methotrexate Sodium			S	Oral	25 Mg, Q.Wk.		Not Reported	
Joint Swelling; Limb	Methotrexate Sodium			S	Oral	25 Mg, Qd		Not Reported	
Deformity; Loss Of	Methotrexate Sodium			S	Oral	25 Mg, Unk		Not Reported	
Personal Independence In	Methotrexate Sodium			S	Unknown	20 Mg, Q.Wk.		Not Reported	
Daily Activities; Malaise;	Methotrexate Sodium			S	Unknown	12.5 Mg, Q.Wk.		Not Reported	
Mood Swings;	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported	
Musculoskeletal Stiffness;	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qd		Not Reported	
Nasopharyngitis; Nausea;	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Neck Deformity; Neck	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Mass; Pain; Pain In									
Extremity; Peripheral									
Swelling; Rheumatoid									
Arthritis; Rheumatoid									
Factor Positive; Stress;									
Swelling; Therapeutic									
Product Effect Decreased;									
Therapeutic Product Effect									
Incomplete; Therapy Non-									
Responder; Treatment									
Failure; Unevaluable									
Event; Vomiting									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Gold	S	Unknown	Unk	Not Reported
Indocid /00003801/	S	Unknown	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Arava	S	Oral	30 Mg, Qd	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Cymbalta	C	Oral	30 Mg, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Folic Acid	C	Oral	Unk, Q.Wk.	Not Reported
Rituxan	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	14243135	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP021933		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
	Hydroxychloroquine			S	Unknown	200 Mg, Unk		Apotex	
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex	
	Leflunomide			S	Unknown	10 Mg, Q.O.D.		Apotex	
	Leflunomide			S	Unknown	5 Mg, Q.O.D.		Apotex	
	Leflunomide			S	Unknown	10 Mg, Qd		Apotex	
	Doxycycline			S	Unknown	50 Mg, Unk		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enbrel	S	Unknown	Unk, Q.Wk.	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Unknown	0.8 Mg, Unk	Not Reported
Humira	S	Unknown	40 Mg, Unk	Not Reported
Methotrexate Sodium	S	Unknown	15 Mg, Q.Wk.	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Simponi	C	Subcutaneous	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Sulfasalazine	C	Unknown	Unk, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	14804432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110773			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Folic Acid	C	Unknown	Not Reported
Tofacitinib Citrate	C		Not Reported
Abatacept	C		Not Reported
Leflunomide	C	Unknown	Not Reported
Therapy Duration: 549.0 Nos			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15041745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2142618		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15260270	EXPEDITED (15-DAY)		HO	CA-ROCHE-2164477		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; Drug	Actemra	S	Unknown	Not Reported
Ineffective; Fall; Fatigue;	Actemra	S	Unknown	Not Reported
Femur Fracture;	Actemra	S	Unknown	Not Reported
Osteoporosis; Pain; Rash;	Actemra	S	Unknown	Not Reported
Synovitis	Actemra	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15411424	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186685		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Blood	Actemra			S	Unknown			Not Reported
Creatinine Increased;	Rituxan			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Diarrhoea;	Enbrel			S	Unknown			Not Reported
Drug Ineffective; Knee	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Arthroplasty; Limb	Orencia			S	Unknown			Not Reported
Discomfort;	Simponi			S	Subcutaneous			Not Reported
Musculoskeletal								
Discomfort; Pain;								
Pharyngeal Oedema;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Penicillin G [Benzylpenicillin]	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15412513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2186027		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Lymphadenectomy; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Toe Amputation	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Restasis			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15417133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2188024		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15438204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190752			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown	Dosage Form: Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Sulfasalazine	C	Unknown	Dosage Form: Not Specified	Not Reported
	Wellbutrin	C	Unknown		Not Reported
	Xeljanz	C	Unknown	Tablet Extended Release	Not Reported
	Bupropion	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	15751882	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181226205		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Remicade			S	Intravenous (not otherwise specified)			Janssen
Alopecia; Arthralgia; Blood Cholesterol Increased;	Simponi			S	Subcutaneous			Janssen
Contraindicated Product Administered; Decreased Appetite; Drug Ineffective;	Simponi			S	Intravenous (not otherwise specified)			Janssen
Exposure During Pregnancy; Fatigue;	Stelara			S	Subcutaneous			Janssen
General Physical Health Deterioration;	Stelara			S				Janssen
Glossodynia; Headache;	Reactine Unspecified (Cetirizine Dihydrochloride)			S	Unknown			Johnson And Johnson
Hypersensitivity;	Enbrel			S	Subcutaneous			Not Reported
Hypertension;	Actemra			S	Unknown			Not Reported
Hypoaesthesia; Joint Swelling; Malaise; Mobility Decreased;	Cimzia			S	Subcutaneous			Not Reported
Musculoskeletal Stiffness; Off Label Use; Pain;	Cimzia			S				Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pemphigus; Pericarditis;	Humira	S	Subcutaneous	Not Reported
Product Use Issue; Rash;	Orencia	S	Subcutaneous	Not Reported
Rheumatic Fever;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rheumatoid Arthritis;				
Swelling; Swollen Joint	Xeljanz	S	Oral	Not Reported
Count Increased;	Apo Prednison	S	Unknown	Not Reported
Synovitis; Systemic Lupus	Cetirizine Hydrochloride	S	Unknown	Not Reported
Erythematosis;	Arava	S	Oral	Not Reported
Therapeutic Product Effect	Arava	S		Not Reported
Decreased; Treatment	Cortisone Acetate	S	Unknown	Not Reported
Failure; Type 2 Diabetes	Folic Acid	S	Unknown	Not Reported
Mellitus	Fosamax	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Otezla	S	Oral	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
W/Pseudoephedrine Hy	S	Unknown	Not Reported
Topicort /00370301/	S	Unknown	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Salazopyrine	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Dexamethasone	C	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
W/Dextropropoxyphene			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	16387997	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR- APL-2019-029784		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bloody Discharge; Drug Hypersensitivity; Drug Intolerance; Fatigue; Hypersensitivity; Infection; International Normalised Ratio Fluctuation; Lyme Disease; Nausea; Therapeutic Product Effect Incomplete; Vomiting	Celecoxib Capsules			S	Oral	200 Milligram, Once A Day		Aurobindo
	Levofloxacin Tablet			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Intravenous (not otherwise specified)	5 Milligram		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Arthrotec			S	Unknown	Unk		Not Reported
	Bisoprolol Fumarate			S	Unknown	Unk		Not Reported
	Ceclor			S	Unknown	Unk		Not Reported
	Cefaclor			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	200 Milligram, Once A Day		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported

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Erythromycin	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	400 Milligram	Not Reported
Leflunomide Sandoz	S	Unknown	Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported
Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
Meperidine Hydrochloride	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	20 Milligram, Every Week	Not Reported
Norfloxacin	S	Unknown	400 Milligram	Not Reported
Norfloxacin	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	400 Milligram, Once A Day	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Bisoprolol	S	Unknown	Unk	Not Reported
Erythro Base	S	Unknown	Unk	Not Reported
Act Diclo Miso	S	Unknown	Unk	Not Reported
Apo-Bisoprolol	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17024875	EXPEDITED (15-DAY)		OT	CA-ROCHE-2461902			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

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Xeljanz			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17025673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2460748			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17088391	EXPEDITED (15-DAY)		DS	CA-ROCHE-2475266		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Alendronate Sodium			S	Unknown			Not Reported	
	Apo-Ibuprofen			S	Oral			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Apremilast			S	Unknown			Not Reported	
	Apremilast			S	Unknown			Not Reported	
	Apremilast			S				Not Reported	
	Ciclosporin			S	Unknown			Not Reported	



Detailed Report

Erythema; Granuloma	Ciclosporin	S	Unknown	Not Reported
Skin; Headache;	Cimzia	S	Subcutaneous	Not Reported
Hypercalcaemia;	Codeine	S	Unknown	Not Reported
Inflammation; Infusion	Enbrel	S	Subcutaneous	Not Reported
Related Reaction; Loss Of	Enbrel	S	Unknown	Not Reported
Personal Independence In	Enbrel	S	Unknown	Not Reported
Daily Activities; Nausea;	Humira	S	Subcutaneous	Not Reported
Panniculitis; Peripheral	Humira	S		Not Reported
Swelling; Psoriatic	Hydroxychloroquine	S	Unknown	Not Reported
Arthropathy; Rash; Rash	Ibuprofen	S	Oral	Not Reported
Pruritic; Red Blood Cell	Infliximab	S	Oral	Not Reported
Sedimentation Rate;	Leflunomide	S	Oral	Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Unknown	Not Reported
Rheumatoid Nodule; Skin	Methotrexate	S	Unknown	Not Reported
Necrosis; Skin Ulcer;	Methotrexate	S	Unknown	Not Reported
Synovitis; Tendonitis;	Methotrexate	S	Unknown	Not Reported
Tenosynovitis; Tongue	Methotrexate	S	Unknown	Not Reported
Disorder; Ulcer	Methotrexate	S	Unknown	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Colchicine	C	Oral	Not Reported
Dexilant	C		Not Reported
Febuxostat	C		Not Reported
Folic Acid	C		Not Reported
Gravol	C		Not Reported
Mogadon	C	Oral	Not Reported
Nitrazepam	C	Unknown	Not Reported
Oxycodone	C		Not Reported
Prednisone	C		Not Reported
Uloric	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17235421	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508675		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Arthrotec			C	Oral			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17245567	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512065		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Contraindicated Product Administered; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17279295	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518789			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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Vomiting	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17338159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530847		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

Xeljanz			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17358684	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533757			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bronchitis; Joint Swelling; Nausea; Nephrolithiasis; Pneumonia; Pyelonephritis; Rash; Urosepsis	Actemra			S	Intratumor			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17360983	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531687		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Certolizumab Pegol			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Naproxen	C		Not Reported
Prednisone	C	Unknown	Not Reported
Rituxan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17399434	EXPEDITED (15-DAY)		OT	CA-ROCHE-2539634		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Discolouration; Skin Disorder; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	8.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Lasix [Furosemide]			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapeutic Product Effect Decreased; Therapeutic Response Decreased;	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Therapy Non-Responder;	Naprosyn [Naproxen]	C		Not Reported
Tooth Disorder;	Oxycontin	C		Not Reported
Toothache; Weight Increased	Oxyneo	C		Not Reported
	Diphenhydramine Hydrochloride	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17422945	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-010439		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Orencia			S	Subcutaneous	125 Milligram		Bristol Myers Squibb
	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Methotrexate			C	Subcutaneous	20 Milligram		Not Reported
	Neoral			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

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Sulfasalazine	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral		Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported
Rabeprazole Sodium	C	Oral	20 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17423321	EXPEDITED (15-DAY)	OT		CA-ROCHE-2542982		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Emotional Disorder; Herpes Zoster; Hypothyroidism; Immobile; Inappropriate Schedule Of Product Administration; Injury; Malignant Melanoma; Product Dose Omission; Rheumatoid Arthritis; Sensitivity To Weather Change; Toe Amputation	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C				Not Reported
	Prednisone			C	Oral			Not Reported
	Restasis			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17465564	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY-		71 YR	Female	CAN

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Detailed Report

BMS-2019-025776

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	10 Milligram		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral	25 Milligram, Qwk		Not Reported
	Methotrexate			S	Unknown	22.5 Milligram		Not Reported
	Methotrexate			S	Oral	25 Milligram, Qd		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram, Bid		Not Reported
	Prednisone			C	Oral	5 Milligram		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17682579	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANSZ PHARMA-202003002825			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Lung Assist Device Therapy; Off Label Use; Pneumonia; Pulmonary Embolism; Respiratory Failure	Hydroxychloroquine			S		600 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Amikacin			S	Intravenous (not otherwise specified)	2200 Mg, Qd		Not Reported

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Detailed Report

Furosemide	C	Unk	Not Reported
Retinol	C	Unk	Not Reported
Cisatracurium	C	Unk	Not Reported
Midazolam	C	Unk	Not Reported
Morphine	C	10 Mg	Not Reported
Macrogol	C	Unk	Not Reported
Paracetamol	C	Unk	Not Reported
Amiodarone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17690932	EXPEDITED (15-DAY)		OT	CA-ROCHE-2584270			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Contraindicated Product Administered; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17715901	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1228878		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported

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Prolonged; Sudden Death	Salbutamol (2297a)	S	Respiratory (inhalation)	0.1 Mg	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Mg, Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	Not Reported
	Propofol (2373a)	S	Intravenous (not otherwise specified)		Not Reported
	Metoclopramida (1958a)	S	Intravenous (not otherwise specified)	10 Mg, Metoclopramida (1958a)	Not Reported
	Ipratropio Bromuro (1067br)	C	Respiratory (inhalation)	20 Mcg	Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous		Not Reported
	Cefotaxima (3840a)	C	Intravenous drip	4gram	Not Reported
	Midazolam (2256a)	C	Intravenous drip	100 Mg	Not Reported
	Tocilizumab (8289a)	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17722969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590358			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17743628	EXPEDITED (15-DAY)	CA		DE-UCBSA-2020017797			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Talipes	Certolizumab Pegol			S	Transplacental	Unknown Dose		Not Reported
	Prednisolone			S	Transplacental	Unknown Dose		Not Reported
	Hydroxychloroquine			S	Transplacental	Unknown Dose		Not Reported
	Sulfasalazine			S	Transplacental	Unknown Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17753395	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-021940		54 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperkalaemia	Perindopril			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17753415	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-021808		58 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day		Aurobindo
	Kaletra			S	Oral	4 Dosage Form, Once A Day		Not Reported
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17753627	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022319		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17753673	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-022323		71 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported	
	Tocilizumab			S				Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754072	EXPEDITED (15-DAY)		HO, LT	SI-TEVA-2020-SI-1233311		48 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Thrombocytopenia; Thrombocytopenia	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg		Teva	
	Kaletra (80 Mg + 20 Mg) / MI			S	Oral	(80mg+20mg)/MI Oral Solution, Dose 400mg/100 Mg, 1 Dosage Forms		Not Reported	
	Piperacillin/Tazobactam Esmeron			C				Not Reported	
				C				Not Reported	

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	Metoclopramid	C		Not Reported
	Analgin	C		Not Reported
	Pantoprazole	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754345	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592877			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754382	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004842			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Thyroid Stimulating Hormone Decreased; Depersonalisation/Derealisation Disorder; Disturbance In Attention; Dyspnoea; Fatigue; Heart Rate Increased; Inflammation; Malaise; Somnolence; Weight Increased	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754566	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593705			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Endocervical	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Rituxan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754573	EXPEDITED (15-DAY)		DS	CA-ROCHE-2593227			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Arthroplasty; Contraindicated Product Administered; Foot Deformity; Loss Of Consciousness; Mobility Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

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Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754642	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593253			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	92.0 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754657	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591253		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>



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Myochrysine	S	Intramuscular	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Rituximab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754953	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593494			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Pulmonary Toxicity; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

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07-May-2020	17754966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593515			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Apo-Ramipril			S	Unknown			Not Reported	
	Dorzolamide;Timolol			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Levothyroxine Sodium			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754972	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010524			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Finger Deformity; Hand Deformity; Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Leflunomide			S	Unknown	Unk		Apotex	
	Methotrexate			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754993	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1230791		47 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	

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	Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Hidroxicloroquina (2143a)	S			Teva
	Paracetamol (12a)	S	Oral	3 Gram Daily;	Not Reported
	Dexketoprofeno (7312a)	S	Intravenous (not otherwise specified)	75 Milligram Daily;	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Tocilizumab (8289a)	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755011	EXPEDITED (15-DAY)	DE		NVSC2020IR111441		9 YR	Male	IRN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Fungal Infection	Hydroxychloroquine			S	Oral			Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755019	EXPEDITED (15-DAY)	OT		NVSC2020US121646		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cornea Verticillata	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	600 Mg, Bid		Novartis	
	Everolimus			S	Unknown	10 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755052	EXPEDITED (15-DAY)	OT		CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-034382			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb	
Alopecia; Anti-Cyclic Citrullinated Peptide	Paracetamol			S	Unknown			Bristol Myers Squibb	
Antibody Positive;	Actemra			S	Unknown			Not Reported	
Arthropathy; Condition Aggravated; Discomfort;	Apo-Prednisone			S	Unknown			Not Reported	

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Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Arava	S	Oral	20 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	25 Milligram	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cortisone	S	Unknown	Unk	Not Reported
	Cortisone Acetate	S	Unknown	25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Folic Acid	S	Oral	5 Milligram	Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Golimumab	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	Unk, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Milligram, Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous drip	Unk	Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral	1 Gram 2 Every 1 Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfathalidine	S	Unknown		Not Reported
Topicort [Hydrocortisone Acetate]	S	Unknown	Unk	Not Reported
Topicort [Hydrocortisone Acetate]	S	Subcutaneous	Unk	Not Reported
Xeljanz	S	Unknown	5 Milligram 2 Every 1 Day	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C	Unknown		Not Reported
Salazopyrina	C	Unknown		Not Reported
Tofacitinib Citrate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755116	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230945		60 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported

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Tocilizumab (8289a)			S	Intravenous (not otherwise specified)		600 Mg	Not Reported		
Tocilizumab (8289a)			S						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755117	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1231564		43 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Paracetamol (12a)			S	Oral	3 Gram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755120	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593218		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	

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Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592731		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug-Induced Liver Injury; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 6.0 Years		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590945		49 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Chest Pain; Drug Ineffective; Pain; Spinal Compression Fracture; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755361	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1231568		56 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Daily		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500mg Daily		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Anakinra (2699a)			S	Subcutaneous	100 Mg		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Daily		Not Reported
	Tocilizumab (8289a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755393	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593389		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Adverse Drug Reaction;	Actemra	S	Unknown	Not Reported
Contraindicated Product	Arava	S	Unknown	Not Reported
Administered; Drug	Enbrel	S	Unknown	Not Reported
Ineffective; Drug	Humira	S	Subcutaneous	Not Reported
Intolerance; Extremity	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Contracture; Nausea;	Leflunomide	S	Unknown	Not Reported
Psoriasis; Pustular	Methotrexate	S	Unknown	Not Reported
Psoriasis; Rheumatoid	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Arthritis; Scar; Vomiting	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Cymbalta	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755414	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593685			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Drug	Enbrel			S	Subcutaneous			Not Reported
Ineffective; Rheumatoid	Hydroxychloroquine			S	Unknown			Not Reported
Arthritis; Therapeutic	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Response Decreased;	Methotrexate			S	Subcutaneous			Not Reported
Treatment Failure	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593751		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Contraindicated Product Administered; Drug Ineffective; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755505	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594111		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	84.0 Days		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown	171.0 Days		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sodium Aurothiomalate			S	Parenteral			Not Reported	

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Sulfasalazine			S		Unknown			Not Reported	
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07-May-2020	17755896	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594375		36 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Infection; Insomnia; Loss Of Personal Independence In Daily Activities	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip	Solution Intravenous		Not Reported	
	Sodium Aurothiomalate			S	Intramuscular			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756052	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020181655		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756057	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020181658		50 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accommodation Disorder; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756170	EXPEDITED (15-DAY)			US-ADVANS PHARMA-202004003663			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Skin Exfoliation	Hydroxychloroquine			S				Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756177	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1045121		21 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Ambisome /00057501/			S	Intravenous (not otherwise specified)	Unk		Mylan	
	Hidroxicloroquina /00072601/			S	Oral	400mg/24h		Mylan	
	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756292	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFM-2020-13035			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Propranolol			S	Oral	20 Mg, Every 12 Hours		Pierre Fabre Medicament	
	Laroxyl			S	Oral	15 Gtt Daily		Not Reported	
	Plaquenil			S	Oral	400 Mg, Every 12 Hours		Not Reported	
	Zithromax			S	Oral			Not Reported	
	Paracetamol			C	Oral	Prn		Not Reported	
	Pantoprazole			C	Oral	20 Mg Daily		Not Reported	
	Oxygen			C	Respiratory (inhalation)	1 L Every Min		Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591074			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Prednisone			S	Oral			Not Reported	
Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported	

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756579	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231653		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Finger Deformity; Limb Operation; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria; Wrist Surgery	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756591	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231662		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756612	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592410		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Adverse Drug Reaction;	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 198.0 Days		Not Reported
Back Pain; Blood Pressure Increased; Bone Disorder;	Arava			S	Oral			Not Reported
Contusion; Crying; Drug Ineffective; Dysphagia;	Enbrel			S	Subcutaneous			Not Reported
Femur Fracture; Gait Disturbance;	Humira			S	Subcutaneous			Not Reported
Haemorrhage;	Humira			S	Subcutaneous	Therapy Duration: 156.0 Days		Not Reported
Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Intervertebral Disc Degeneration; Oedema	Methotrexate			S	Unknown			Not Reported
Peripheral; Osteoarthritis; Pain; Pruritus; Rash;	Methotrexate			S	Unknown			Not Reported
Spinal Disorder; Spinal	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Operation; Swelling; Therapy Non-Responder	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756749	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593985			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756797	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2594249		48 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Bupropion			C				Not Reported	
	Esomeprazole			C	Unknown	Not Specified		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Levothyroxine Sodium			C				Not Reported	
	Naproxen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756818	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1045233		81 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral	10 Milligram, Qd		Not Reported	
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan	
	Azithromycine Sandoz /00944304/			S	Oral	250 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756918	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592918			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported	

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Arthralgia; Blood	Rituximab	S	Intravenous drip	Not Reported
Creatinine Increased;	Ciclosporin	S	Unknown	Not Reported
Contraindicated Product	Enbrel	S	Unknown	Not Reported
Administered; Drug	Humira	S	Unknown	Not Reported
Hypersensitivity; Drug	Hydroxychloroquine	S	Unknown	Not Reported
Ineffective; Drug	Methotrexate	S	Unknown	Not Reported
Intolerance; Loss Of	Orencia	S	Unknown	Not Reported
Personal Independence In	Sulfasalazine	S	Unknown	Not Reported
Daily Activities; Mobility	Tofacitinib	S	Unknown	Not Reported
Decreased;	Acetaminophen	C		Not Reported
Musculoskeletal Pain;	Gabapentin	C		Not Reported
Neck Pain; Pain In	Xeljanz	C		Not Reported
Extremity; Pain In Jaw;				
Rheumatoid Arthritis				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17756998	EXPEDITED (15-DAY)		LT	CA-BAUSCH-BL-2020-013031		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Minocycline Hydrochloride			S	Unknown			Not Reported
Arthropathy; C-Reactive	Actemra			S	Unknown			Not Reported
Protein Abnormal;	Actemra			S				Not Reported
Contraindicated Product	Anakinra			S	Unknown			Not Reported
Administered; Deep Vein	Anakinra			S				Not Reported
Thrombosis; Diverticulitis;	Arava			S	Unknown			Not Reported
Drug Hypersensitivity;	Arava			S	Unknown			Not Reported
Drug Ineffective; Drug	Arava			S	Unknown			Not Reported
Intolerance; Feeling	Cannabis Sativa			S	Unknown			Not Reported
Abnormal; Haemoglobin	Enbrel			S	Subcutaneous			Not Reported
Decreased; Herpes	Enbrel			S	Unknown			Not Reported
Zoster; Intentional Product	Gold			S	Unknown			Not Reported
Use Issue; Interstitial Lung	Humira			S	Subcutaneous			Not Reported
Disease; Joint	Humira			S	Unknown			Not Reported
Arthroplasty; Joint	Hydroxychloroquine Sulphate			S	Oral			Not Reported
Swelling; Knee								
Arthroplasty; Myocardial								
Infarction; Off Label Use;								
Pain; Photosensitivity								

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Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulphate	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757193	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593721		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Colitis Ulcerative; Drug Ineffective; Herpes Zoster; Insomnia; Joint Swelling; Malaise; Musculoskeletal Pain; Off Label Use; Pain In Extremity; Peripheral Swelling; Pharyngeal Oedema; Poor Quality Sleep; Pruritus; Red Blood Cell Sedimentation Rate Abnormal; Restless Legs Syndrome; Treatment Failure	Actemra Codeine Enbrel Hydroxychloroquine Hydroxychloroquine Sulfate Methotrexate Methotrexate Orencia Plaquenil [Hydroxychloroquine Sulfate]	S S S S S S S S S	Intravenous (not otherwise specified) Unknown Subcutaneous Unknown Unknown Oral Unknown Intravenous (not otherwise specified) Unknown	Therapy Duration: 3.0 Months Therapy Duration: 4.0 Years Therapy Duration: 11.0 Months	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757227	EXPEDITED (15-DAY)		OT	ES-SA-2020SA118630		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi	
	Hydroxychloroquine			S				Sanofi	
	Hydroxychloroquine			S				Sanofi	
	Sulpiride			S	Oral	50 Mg Every 8 Hours		Not Reported	
	Enoxaparin Sodium			S	Subcutaneous	40 Mg Day		Sanofi	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757238	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA- 1231627		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone	Alendronate Sodium Codeine Methotrexate Methotrexate			S S S S	Unknown Unknown Subcutaneous Subcutaneous			Actavis Not Reported Barr Barr	

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Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Subcutaneous		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Methotrexate	S	Subcutaneous		Barr
	Apo-Leflunomide	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S			Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Remicade	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate	C	Unknown		Not Reported

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Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C		Not Reported

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07-May-2020	17757241	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231621		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757245	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231635			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rheumatoid Arthritis	Codeine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Barr	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757282	EXPEDITED (15-DAY)		OT	CA-SA-2020SA117632			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosis; Wound	Desoximetasone			S	Oral			Sanofi	
	Arava			S	Oral			Sanofi	
	Cetirizine Hydrochloride			S				Not Reported	
	Alendronate Sodium			S	Oral			Not Reported	
	Folic Acid			S				Not Reported	
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S		Unk		Sanofi	
	Methotrexate			S	Oral			Not Reported	
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Actemra			S				Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tofacitinib Citrate	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757316	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231661			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Colectomy; Diarrhoea; Drug Hypersensitivity; Drug Hypersensitivity; Drug Hypersensitivity; Speech Disorder Developmental; Treatment Failure; Treatment Failure	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Imuran			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757323	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232012			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Milligram Daily;		Barr
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757399	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1231650		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Codeine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Alendronate			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

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Rituximab	S	Unknown	2000 Milligram Daily;	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Ciclosporin	C			Not Reported
Prednisone	C			Not Reported
Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757479	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231761			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Macular Degeneration; Pancreatitis	Prednisone			S	Unknown			Actavis
	Leflunomide			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757486	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232100		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bronchitis;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
Contraindicated Product Administered; Cough;	Leflunomide			S	Unknown			Barr
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Influenza Like Illness; Interstitial Lung Disease; Malaise; Mass Excision; Nodule;	Actonel			S	Oral			Not Reported
Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased	Actonel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Methotrexate	S	Oral	3.2143 Milligram Daily;	Not Reported
Novo-Rythro	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Bupropion	C	Unknown		Not Reported
Cannabis Sativa	C	Unknown		Not Reported
Celebrex	C	Unknown	400 Milligram Daily;	Not Reported
Celebrex	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Hydroxychloroquine	C	Oral	400 Milligram Daily;	Not Reported
Wellbutrin	C	Unknown		Not Reported
Wellbutrin	C	Unknown	300 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757490	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232011		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Off Label Use; Rheumatoid Arthritis; Tuberculin Test Positive	Leflunomide			S	Oral	10 Mg		Barr
	Methotrexate			S	Unknown	5 Mg		Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown	Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Prednisone			C	Unknown	50 Milligram Daily;		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757559	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020179134			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	
	Hydroxychloroquine Sulfate			S				Not Reported	
	Morphine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757730	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395337-00		68 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Roactemra			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757800	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3395439-00		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757860	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395468-00		70 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hypertransaminasaemia; Off Label Use	Kaletra	S	Oral	Not Reported
	Zitromax Avium	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17758020	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231932			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Leflunomide			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Tenofovir Disoproxil Fumarate			C				Not Reported
	Xeljanz			C				Not Reported
	Zopiclone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17758024	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231959			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance;	Leflunomide			S	Unknown			Barr

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Gastrointestinal Disorder; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Sulfasalazine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17758500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594137		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	4.0 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17758595	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593996		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Intolerance; Investigation Abnormal; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapy Non- Responder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported

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Remicade			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17758709	EXPEDITED (15-DAY)		OT	CH-ABBVIE-20K-151-3392070-00		82 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S	Oral			Not Reported	
	Erythromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Actemra			C	Intravenous drip			Not Reported	
	Tazobac			C		2.0gr / 0.25mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17758863	EXPEDITED (15-DAY)		OT	RO-AUROBINDO-AUR-APL-2020-024107			Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Rupture; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Zinc			S	Unknown	Unk		Not Reported	
	Vitamin C			S	Unknown	Unk		Not Reported	
	Algozone			S	Unknown	Unk		Not Reported	
	Norvir			S	Oral	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	
	Lopinavir			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17759741	DIRECT	Y	DE			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Fibrinogen Decreased; Blood Lactate Dehydrogenase Increased; Bundle Branch Block Right; Covid-19 Pneumonia; Dyspnoea; Electrocardiogram Qt Prolonged; Fibrin D Dimer Increased; Hypertension; Hypokalaemia; Hypoxia; Leukocytosis; Myocardial Infarction; Oedema Peripheral; Sars-Cov-2 Test Positive; Serum Ferritin Increased; Sinus Tachycardia	Hydroxychloroquine Sulfate Tablets Ceftriaxone Vancomycin Azithromycin Tocilizumab Piperacillin/Tazobactam Acetaminophen Albuterol Enoxaparin Ipratropium Losartan Oxymetazoline Kcl Propofol Norepinephrine Oseltamivir	S C C C C C C C C C C C C C C C	Oral	Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	11173619	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1589861		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Disability; Drug Ineffective;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Dyspnoea; Dyspnoea; Impaired Work Ability;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Joint Lock; Joint Swelling;	Enbrel			S	Subcutaneous			Not Reported
Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass;	Enbrel			S	Subcutaneous			Not Reported
Mobility Decreased;	Methotrexate			S	Oral			Not Reported
Musculoskeletal Stiffness;	Methotrexate			S	Oral			Not Reported
Pain; Peripheral Swelling;	Methotrexate			S	Subcutaneous			Not Reported
Physical Disability; Rash;	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Skin Mass; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapy Non-Responder; Therapy Non-Responder	Arava	S	Oral		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cimzia	S	Unknown		Not Reported
	Cimzia	S	Unknown	Therapy Duration: 10.0 Month	Not Reported
	Cimzia	S	Unknown	Single Use Pre-Filled Syringe	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown	5-20 Mg As Necessary	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Sulfasalazine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	11820435	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675314		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Dyspepsia; Nausea; Thrombosis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment Failure	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	Does Not Tolerate 1 G Bid	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	11999096	EXPEDITED (15-DAY)		DS	CA-ROCHE-1703918		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Anakinra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Methotrexate			C C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	12852770	EXPEDITED (15-DAY)		LT, OT	CA-ROCHE-1695185		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate Sodium			S	Oral	4 Pills		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Kidney Infection; Musculoskeletal Disorder; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13015516	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865715		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Joint Arthroplasty; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duratin: 6 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Gp2013			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Leflunomide	C	Unknown	Therapy Duration: 6 Months	Not Reported
	Xeljanz	C	Oral		Not Reported
	Celebrex	C			Not Reported
	Diclofenac	C			Not Reported
	Lyrica	C			Not Reported
	Sulfasalazine	C			Not Reported
	Valsartan	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13053281	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870963			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported
Folic Acid	C	Oral	Not Reported
Pantoprazole	C		Not Reported
Tenofovir Disoproxil Fumarate	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Oral	Not Reported
Tenofovir Disoproxil	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13067695	EXPEDITED (15-DAY)		OT	CA-ROCHE-1870959			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Nodule; Therapeutic Product Effect Decreased; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13201712	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889172			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Rituxan			S	Intravenous drip			Not Reported
Emotional Disorder;	Actemra			S	Unknown			Not Reported
Herpes Zoster;	Enbrel			S	Subcutaneous			Not Reported
Hypothyroidism; Immobile;	Humira			S	Subcutaneous			Not Reported
Inappropriate Schedule Of	Methotrexate			S	Oral			Not Reported
Product Administration;	Sulfasalazine			S	Oral			Not Reported
Injury; Lymphadenectomy;	Hydroxychloroquine			S	Oral			Not Reported
Malignant Melanoma;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Product Dose Omission;	Folic Acid			C				Not Reported
Rheumatoid Arthritis;	Prednisone			C	Unknown			Not Reported
Sensitivity To Weather	Synthroid			C				Not Reported
Change; Toe Amputation	Restasis			C				Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13253859	EXPEDITED (15-DAY)		OT	CA-ROCHE-1894972		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cytology	Actemra			S	Unknown			Not Reported
Abnormal; Drug	Rituxan			S	Intravenous (not			Not Reported
Ineffective; Drug					otherwise specified)			
Intolerance; Laboratory	Rituxan			S	Intravenous (not			Not Reported
Test Abnormal;					otherwise specified)			
Neuropathy Peripheral;	Rituxan			S	Unknown			Not Reported
Prerenal Failure; Renal	Rituxan			S	Unknown			Not Reported
Disorder; Therapeutic	Rituxan			S	Unknown			Not Reported
Product Effect Decreased;	Arava			S	Unknown			Not Reported
Treatment Failure	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cimzia	S	Unknown		Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Unknown		Not Reported
Leflunomide	S	Unknown	Therapy Duration: 365.0 Nos	Not Reported
Methotrexate	S	Unknown	Therapy Duration: 19.0 Year(S)	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Therapy Duration: 19.0 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
Gold	S	Unknown		Not Reported
Gold	S			Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown	Therapy Duration: 365.0	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C			Not Reported
Xeljanz	C	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13262211	EXPEDITED (15-DAY)		OT	CA-ROCHE-1662402		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Anakinra			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13704441	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955227			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Actemra			S	Unknown			Not Reported	
	Actemra			S				Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Solution		Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Anakinra			S				Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Sulfasalazine			S				Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disease; Joint Swelling;	Apo-Leflunomide	S	Unknown	Not Reported
Myocardial Infarction; Off	Apo-Leflunomide	S		Not Reported
Label Use; Pain;	Enbrel	S	Subcutaneous	Not Reported
Photosensitivity Reaction;	Enbrel	S		Not Reported
Pulmonary Embolism;	Humira	S	Subcutaneous	Not Reported
Pulmonary Thrombosis;	Humira	S	Subcutaneous	Solution
Red Blood Cell	Humira	S	Subcutaneous	Not Reported
Sedimentation Rate	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Increased; Renal Failure;	Hydroxychloroquine Sulfate	S		Not Reported
Sepsis; Stomatitis;	Ilaris	S	Subcutaneous	Not Reported
Terminal State;	Ilaris	S	Subcutaneous	Not Reported
Thrombosis; Urticaria	Ilaris	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported
	Marijuana	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfate]				
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S			Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S			Not Reported
Xeljanz	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	13868918	EXPEDITED (15-DAY)		OT	CA-ROCHE-1975064			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Cortisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	14678468	EXPEDITED (15-DAY)		OT	CA-ROCHE-2089917		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Dyspepsia;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported

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Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Azathioprine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	14950745	EXPEDITED (15-DAY)		OT	CA-ROCHE-2131646		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Stomatitis	Rituximab			S	Unknown			Not Reported
	Abatacept			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	15275955	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167429		54 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hip Arthroplasty; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Prednisone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	15393834	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184304		43 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain;	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported	
	Arava			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Risedronate Sodium	C		Not Reported
	Actonel	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	15438740	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190735			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Visual Impairment	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	15470422	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-014635		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose	Xyrem			S	Oral	2.5 G, Bid		Jazz	
Fluctuation; Diarrhoea;	Xyrem			S	Oral	Dose Adjustment		Jazz	
Loss Of Consciousness;	Xyrem			S	Oral	6 G, First Dose		Jazz	
Malabsorption; Nausea;	Xyrem			S	Oral	6.5g, Second Dose		Jazz	
Osteoarthritis; Retching;	Xyrem			S	Oral	4.5 Gram First Dose		Jazz	
Systemic Lupus	Xyrem			S	Oral	3.5 Gram Second Dose		Jazz	
Erythematous; Vomiting;	Xyrem			S	Oral	Unknown		Not Reported	
Weight Decreased	Pilocarpine			S				Not Reported	
	Promethazine			S				Not Reported	
	Hydroxychloroquine Phosphate			S				Not Reported	
	Xifaxan			C		Unk		Not Reported	
	Vitamin D3			C		Unk		Not Reported	
	Linzess			C		Unk		Not Reported	
	Zanaflex			C		Unk		Not Reported	
	Cyclobenzaprine			C		Unk		Not Reported	
	Zolpidem Tartrate			C		Unk		Not Reported	
	Adderall			C		Unk		Not Reported	
	Advair Hfa			C		Unk		Not Reported	
	Allegra Allergy			C		Unk		Not Reported	
	Metoprolol Tartrate			C		Unk		Not Reported	
	Metoclopramide			C		Unk		Not Reported	
	Rizatriptan			C		Unk		Not Reported	
	Theophylline			C		Unk		Not Reported	
	Biotin			C		Unk		Not Reported	
	Cymbalta			C		Unk		Not Reported	
	Maxalt Mlt			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prevacid	C	Unk	Not Reported
Requip	C	Unk	Not Reported
Singulair	C	Unk	Not Reported
Cyanocobalamin	C	Unk	Not Reported
Xarelto	C	Unk	Not Reported
Xopenex	C	Unk	Not Reported
Zinc Gluconate	C	Unk	Not Reported
Zyrtec	C	Unk	Not Reported
Advair	C	Unk	Not Reported
Ambien	C	Unk	Not Reported
Morphine Sulf	C	Unk	Not Reported
Tramadol Hcl	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	15944441	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA034910		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Clopidogrel Bisulfate			S	Unknown	Unk Unk, Unk		Sanofi
	Furosemide			S	Unknown			Sanofi
	Famotidine			S	Unknown	Unk Unk, Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk Unk, Unk		Not Reported
	Doxycycline			S	Unknown	Unk Unk, Unk		Not Reported
	Trandolapril			S	Unknown	Unk Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk, Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk Unk, Unk		Not Reported
	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Gabapentin			S	Unknown	Unk Unk, Unk		Not Reported

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Esomeprazole Magnesium	S	Unknown	Unk Unk, Unk	Not Reported
Rosuvastatin Calcium	S	Unknown	Unk Unk, Unk	Not Reported
Potassium	S	Unknown	Unk Unk, Unk	Not Reported
Glyceryl Trinitrate	S	Unknown	Unk Unk, Unk	Sanofi
Metoclopramide Hydrochloride	S		Unk Unk, Unk	Not Reported
Trazodone Hydrochloride	S		Unk Unk, Unk	Not Reported
Isosorbide Mononitrate	S		Unk Unk, Unk	Not Reported
Victoza	S	Unknown	Unk Unk, Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qod	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Humira	S			Not Reported
Flomax [Morniflumate]	S	Unknown	Unk Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	16451752	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019048692		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Enbrel			S		Unk		Pfizer
	Pamidronate Disodium			S		Unk		Pfizer
	Xeljanz			S	Unknown	5 Milligram, Bid		Pfizer
	Xeljanz			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S				Pfizer
	Doxycycline			S	Unknown	Unk		Pfizer
	Doxycycline Hyclate			S	Unknown	Unk		Pfizer
	Stelara			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	6-Mercaptopurine Monohydrate			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tenoxicam	S	Unknown	Unk	Not Reported
Bromocriptine	S		Unk	Not Reported
Ustekinumab	S	Unknown	Unk	Not Reported
Colchicine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Azathioprine	S			Not Reported
Ciclosporin	S			Not Reported
Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported
Mercaptopurine	C			Not Reported
Methylprednisolone	C			Not Reported
Sulfasalazine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17024068	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459889			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Rash; Therapeutic Response Decreased; Therapy Non- Responder	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17108802	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-063176			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue;	Diclofenac Sodium			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glossodynia; Hand Deformity; Infusion Related Reaction;	Actemra	S	Unknown	Not Specified	Not Reported
Maternal Exposure During Pregnancy; Pain;	Arava	S	Oral		Not Reported
Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling;	Cetirizine Hydrochloride	S	Unknown		Not Reported
Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Methotrexate	S	Intra-arterial		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Hydroxychloroquine Phosphate	S	Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17240218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2509529		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Feeding Disorder; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Varenicline Tartrate			S	Oral			Not Reported	
	Rituxan			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Acetaminophen			C				Not Reported	
	Acetaminophen;Oxycodone Hydrochloride			C	Oral			Not Reported	
	Esomeprazole Magnesium Trihydrate			C	Oral			Not Reported	
	Esomeprazole Magnesium Trihydrate			C	Unknown			Not Reported	
	Esomeprazole Magnesium Trihydrate			C	Oral			Not Reported	
	Naproxen			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Naproxen	C	Oral	Not Reported
	Naproxen	C	Oral	Not Reported
	Oxycodone Hydrochloride	C		Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Valtrex	C	Oral	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17244861	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510478		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Product Use In Unapproved Indication; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 411.0		Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17245971	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512719			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphthous Ulcer; Drug Ineffective; Mouth Ulceration; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17259394	EXPEDITED (15-DAY)		HO	CA-ROCHE-2518182			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Pain; Nausea; Neck Pain; Pain; Pain In Extremity; Peripheral Swelling; Rash; Therapeutic Product Effect Decreased; Weight Decreased	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17260727	EXPEDITED (15-DAY)		OT	CA-ROCHE-2515953		49 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Synovitis; X- Ray Abnormal	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Penicillin-G			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Calcium			C				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17411839	EXPEDITED (15-DAY)		DS	CA-ROCHE-2546716		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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Enbrel	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Salazopyrin	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Gold	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Bifidobacterium Bifidum	C		Not Reported
Celebrex	C		Not Reported
Loperamide	C		Not Reported
Pantoprazole	C		Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17443400	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552179		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

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		otherwise specified)	
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17484426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559700		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17662183	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202003002382			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Hallucination, Visual; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia	
	Temesta			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17663375	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-018165		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	Unk		Not Reported	
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Once A Day		Not Reported	
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Noradrenaline Tartrate Renaudin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Once A Day		Not Reported	
	Transipeg			C	Oral	Unk		Not Reported	
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Nimbex			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Effexor			C	Oral	Unk		Not Reported	
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk		Not Reported	
Seresta			C	Oral	Unk		Not Reported		

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Rocephin	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17670319	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003746		75 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Ritonavir/Lopinavir			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Enoxaparin Sodium			C	Subcutaneous			Not Reported
	Prednisone			C	Oral			Not Reported
	Ceftriaxone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17692715	EXPEDITED (15-DAY)		HO, OT	FR-ADVANSZ PHARMA-202004002846			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Pneumonia Bacterial; Pneumonia Bacterial; Staphylococcal Bacteraemia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd		Concordia
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported
	Spiramycin			S		6 Mu, Qd		Not Reported
	Vancomycine			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported
	Vancomycine			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17707946	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202004003809			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Discomfort;	Hydroxychloroquine			S	Unknown	Unk		Concordia	
Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17710765	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020055142		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Drug Reaction; Alopecia; Anti-Cyclic Citrullinated Peptide	Cetirizine Hydrochloride			S	Unknown	10 Milligram		Glaxosmithkline	
Antibody Positive; Arthralgia; Discomfort; Drug Ineffective; Drug Intolerance; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis;	Cetirizine Hydrochloride			S				Glaxosmithkline	
	Diclofenac			S	Unknown	Unk		Glaxosmithkline	
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline	
	Cetirizine Hydrochloride + Pseudoephedrine Hydrochloride			S				Glaxosmithkline	
	Pseudoephedrine Hcl			S	Unknown	Unk		Glaxosmithkline	
	Desoximetasone			S	Oral	And Oral		Glaxosmithkline	
	Topicort			S	Subcutaneous	Unk		Glaxosmithkline	
	Topicort			S	Topical	Unk		Glaxosmithkline	
	Folic Acid			S	Unknown	5 Milligram		Glaxosmithkline	
	Folic Acid			S	Oral	25 Milligram		Glaxosmithkline	
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline	
	Cortisone Acetate			S	Unknown	25 Mg		Glaxosmithkline	
	Cimzia (Certolizumab Pegol)			S	Subcutaneous	400 Milligram		Not Reported	

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Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Stelara	S	Subcutaneous	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Remicade	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Humira	S	Subcutaneous	4 Milligram	Not Reported
	Humira	S		40 Milligram	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Unknown	400 Milligram, Once Daily (Qd)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sarilumab	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2x/Day (Bid)	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Once Daily (Qd)	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Sulfathalidine	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Milligram, 2x/Day (Bid)	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Once Daily (Qd)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
	Apo-Prednisone	S	Unknown	40 Milligram	Not Reported
	Apo-Prednisone	S	Unknown	Unk	Not Reported

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Arava	S	Unknown	Unk	Not Reported
Methotrexate	S	Oral	25 Milligram	Not Reported
Methotrexate	S	Subcutaneous	25 Milligram, Weekly (Qw)	Not Reported
Methotrexate	S	Subcutaneous	25 Mg	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

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08-May-2020	17717548	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586707		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17721358	EXPEDITED (15-DAY)		OT	CA-ROCHE-2588511			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17726275	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR- APL-2020-020963		18 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation;	Omeprazole			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Aurobindo

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Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole	S	Intravenous (not otherwise specified)	40 Milligram, Once A Day	Aurobindo
	Hydroxychloroquine Sulfate	S	Unknown	1200 Milligram, Once A Day	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Once A Day	Not Reported
	Midazolam	S	Intravenous (not otherwise specified)	5 Dosage Form, Once A Day (5 Mg/ML, Qd)	Not Reported
	Lovenox	S	Subcutaneous	0.6 Milliliter, Once A Day	Not Reported
	Loxen (Nifedipine Hydrochloride)	S	Intravenous (not otherwise specified)	30 Milligram, Once A Day	Not Reported
	Movicol	S	Unknown	2 Dosage Form (2 Df Bag)	Not Reported
	Diffu K	C	Unknown	3.6 Gram, Once A Day	Not Reported
	Diffu K	C			Not Reported
	Doliprane	C	Unknown	Unk	Not Reported
	Doliprane	C			Not Reported
	Paracetamol	C	Unknown	4 Gram, Once A Day	Not Reported
	Paracetamol	C			Not Reported
	Lasilix	C	Unknown	30 Milligram, Once A Day	Not Reported
	Novorapid	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17729385	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200436819			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Deafness; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17736281	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436855			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17744165	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436847		51 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17744175	EXPEDITED (15-DAY)	HO, LT		CA-JNJFOC-20200436815		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S				Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Canakinumab			S	Subcutaneous			Not Reported
	Canakinumab			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Plaquenil /00072602/	S	Unknown	Not Reported
	Plaquenil /00072602/	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17744178	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436844			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Plaquenil /00072602/			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17744179	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436805			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17744182	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200436802			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Actemra	C	Subcutaneous	Not Reported
Arava	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17744192	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200436812			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosis; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17745328	EXPEDITED (15-DAY)			CH-PFIZER INC-2020175487		51 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
No Adverse Event	Zithromax			S	Oral	500 Mg		Pfizer
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G		Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Intravenous drip	1.2 G		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg (In Total)		Not Reported
	Kaletra			S	Oral	400 Mg		Not Reported
	Kaletra			S	Oral	400 Mg		Not Reported
	Clexane			S	Subcutaneous	40 Mg		Not Reported
	Clexane			S	Subcutaneous	40 Mg		Not Reported
	Clexane			S	Subcutaneous	Unk		Not Reported
	Clexane			S	Subcutaneous	40 Mg		Not Reported
	Perfalgan			S	Intravenous (not otherwise specified)	1 Mg (Max 3x/Day ; As Necessary)		Not Reported
	Ipramol			C		Unk		Not Reported
	Temesta [Lorazepam]			C		Unk		Not Reported
	Tavanic			C		Unk		Not Reported
	Atracurium			C		Unk		Not Reported
	Fentanyl			C		Unk		Not Reported
	Dormicum [Midazolam Maleate]			C		Unk		Not Reported
	Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]			C		Unk		Not Reported
	Colistin			C		Unk		Not Reported
	Torasemide			C		Unk		Not Reported
	Potassium			C		Unk		Not Reported
	Benerva			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Heparin	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Relistor	C	Unk	Not Reported
Novasource Gi Control	C	Unk	Not Reported
Ventoline [Salbutamol]	C	Unk (As Necessary)	Not Reported
Movicol	C	Unk (As Necessary)	Not Reported
Tobramycin	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17747516	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114923			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Cortisone Acetate			S		25 Mg		Not Reported
Alopecia; Anti-Cyclic	Arava			S	Oral	20 Mg		Sanofi
Citrullinated Peptide	Cetirizine Hydrochloride			S		25 Mg		Not Reported
Antibody Positive;	Cetirizine Hydrochloride			S		10 Unk		Not Reported
Condition Aggravated;	Folic Acid			S	Oral	5 Mg		Not Reported
Discomfort; Drug	Hydroxychloroquine Sulfate			S		Unk		Sanofi
Ineffective; Drug	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
Intolerance; Fatigue;	Hydrocortisone Acetate			S	Subcutaneous			Sanofi
Glossodynia; Hand	Methotrexate			S	Oral	Unk Unk, Qd		Not Reported
Deformity; Hepatic	Methotrexate			S	Oral	25 Mg		Not Reported
Enzyme Increased; Hip	Methotrexate			S		Unk		Not Reported
Arthroplasty;	Leflunomide			S		Unk		Sanofi
Hypersensitivity; Infusion	Pseudoephedrine Hydrochloride			S				Sanofi
Related Reaction; Joint	Sarilumab			S				Sanofi
Swelling; Knee	Sulfasalazine			S	Oral	1 Df, 1 Gram		Not Reported
Arthroplasty; Maternal	Sulfasalazine			S		500 Mg		Not Reported
Exposure During								
Pregnancy; Pain;								
Pemphigus; Pericarditis;								
Rash; Rheumatoid								
Arthritis; Rheumatoid								
Factor Positive; Swelling;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Desoximetasone	S	Oral	Unk	Sanofi
	Topicort	S	Subcutaneous		Sanofi
	Acetaminophen	S			Not Reported
	Actemra	S		Unk	Not Reported
	Apo-Prednisone	S			Not Reported
	Diclofenac Sodium	S		Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	20 Mg, Qw	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Fosamax	S	Oral	Unk	Not Reported
	Golimumab	S			Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Methotrexate Sodium	S	Oral	25 Mg	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S		Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Stelara	S		Unk	Not Reported
	Sulfathalidine	S			Not Reported
	Xeljanz	S		5 Mg, Bid	Not Reported
	Salazopyrina	C		Unk	Not Reported
	Tofacitinib Citrate	C		Unk	Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17758660	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-20K-028-3390697-00		62 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthropathy; Back Pain; Body Height Decreased; C-Reactive Protein Decreased; Deep Vein Thrombosis; Depression; Drug Ineffective; Drug Ineffective; Emotional Distress; Emotional Distress; Fatigue; Foot Fracture; Malaise; Osteoporosis; Pelvic Fracture; Pruritus Allergic; Psoriasis; Psoriatic Arthropathy; Quality Of Life Decreased; Rheumatoid Arthritis; Sensitivity To Weather Change; Spinal Fracture	Humira			S	Subcutaneous			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Methotrexate Sodium			C	Oral			Not Reported
	Warfarin			C				Not Reported
Tofacitinib Citrate			C				Not Reported	
Vioxx			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17758765	EXPEDITED (15-DAY)		HO, OT	IT-ADVANS PHARMA- 202004004915			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported
	Heparin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17758901	EXPEDITED (15-DAY)		OT	CH-PFIZER INC- 2020182222		51 YR	Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Hepatocellular	Zithromax			S	Oral	500 Mg		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injury; Hypoxia; Liver Function Test Abnormal	Piperacillin/Tazobactam	S	Intravenous drip	4.5 G	Pfizer
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]	S	Intravenous drip	1.2 G	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	800 Mg (In Total)	Not Reported
	Kaletra	S	Oral	400 Mg	Not Reported
	Kaletra	S	Oral	400 Mg	Not Reported
	Clexane	S	Subcutaneous	40 Mg	Not Reported
	Clexane	S	Subcutaneous	40 Mg	Not Reported
	Clexane	S	Subcutaneous	Unk	Not Reported
	Clexane	S	Subcutaneous	40 Mg	Not Reported
	Perfalgan	S	Intravenous (not otherwise specified)	1 Mg (Max 3xday; As Necessary)	Not Reported
	Ipramol	C		Unk	Not Reported
	Temesta [Lorazepam]	C		Unk	Not Reported
	Tavanic	C		Unk	Not Reported
	Atracurium	C		Unk	Not Reported
	Fentanyl	C		Unk	Not Reported
	Dormicum [Midazolam Maleate]	C		Unk	Not Reported
	Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C		Unk	Not Reported
	Colistin	C		Unk	Not Reported
	Torasemide	C		Unk	Not Reported
	Potassium	C		Unk	Not Reported
	Benerva	C		Unk	Not Reported
	Heparin	C		Unk	Not Reported
	Solu-Medrol	C		Unk	Not Reported
	Novorapid	C		Unk	Not Reported
	Relistor	C		Unk	Not Reported
	Novasource Gi Control	C		Unk	Not Reported
	Ventoline [Salbutamol]	C		Unk (As Necessary)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Movicol	C	Unk (As Necessary)	Not Reported
Tobramycin	C	Unk	Not Reported
Amphotericin B	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17758976	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594187		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759106	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2593615		8 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; General Physical Health Deterioration; Infusion Site Reaction; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not			Not Reported

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		otherwise specified)	
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593284		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Joint Swelling; Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759190	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592797		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Sulfasalazine			C				Not Reported
	Simponi			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594201		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Minocycline	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759235	EXPEDITED (15-DAY)		OT	ES-SA-2020SA118599		45 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759255	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594261		77 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592749		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Drug Intolerance; Joint Swelling; Rheumatoid Factor Positive; X-Ray Abnormal	Actemra			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tofacitinib Citrate			S	Unknown			Not Reported	
	Diovan			C				Not Reported	
	Docosahexaenoic Acid;Eicosapentaenoic Acid			C				Not Reported	
	Sertraline			C	Unknown			Not Reported	
	Valtrex			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759454	EXPEDITED (15-DAY)		DE, OT	MX-ADVANSZ PHARMA-202004004823			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Haemodynamic Instability; Off Label Use; Renal Impairment	Hydroxychloroquine			S		200 Mg, Bid		Concordia	
	Hydroxychloroquine			S				Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759495	EXPEDITED (15-DAY)		HO, OT	ALC2020CA003397			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug	Phenylephrine			S	Unknown	Unk		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg 1 Every 1 Months		Not Reported	

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Hypersensitivity; Drug Ineffective; Drug Intolerance;	Arava	S	Unknown	20.0 Mg	Not Reported
Gastrointestinal Toxicity; Hepatotoxicity; Infection;	Benzalkonium Chloride	S	Unknown		Not Reported
Joint Injury; Joint Stiffness; Joint Swelling;	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr	S	Unknown		Not Reported
Musculoskeletal Pain;	Boric Acid	S	Unknown		Not Reported
Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Cimzia	S	Unknown	Solution Subcutaneous (Single-Use Prefilled Syringe)	Not Reported
	Disodium Edetate	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	40.0 Mg 1 Every 1 Week	Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous	40.0 Mg	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200.0 Mg, Bid	Not Reported
	Methotrexate	S	Oral	15.0 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral	5.0 Mg, Bid	Not Reported
	Rho D Immune Globulin	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Sodium Borate	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib Citrate	S	Unknown	10.0 Mg, Q2w	Not Reported
	Tofacitinib Citrate	S	Unknown	10.0 Mg, Q2w	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	10.0 Mg, Q2w	Not Reported
	Prednisone	C	Unknown		Not Reported
	Celebrex	C	Oral	400.0 Mg	Not Reported

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Ibuprofen	C	Oral	400.0 Mg	Not Reported
Lipitor	C	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759506	EXPEDITED (15-DAY)	OT		CA-ROCHE-2594292			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759507	EXPEDITED (15-DAY)	OT		CA-ROCHE-2594366			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

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Leflunomide	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592791			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Hand Deformity; Impaired Work Ability; Joint Swelling; Polyarthrititis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Frequency: Cyclical		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Indomethacin [Indometacin]			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759786	EXPEDITED (15-DAY)		HO, OT	IT-SA-2020SA115979		76 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Clexane T			S	Subcutaneous	6000 Kiu, Qd		Sanofi
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Amlodipine Besilate			S	Oral	10 Mg, Qd		Not Reported

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Amlodipine Besilate	S	Oral	Unk (Dose Reduced)	Not Reported
Plaquenil	S	Oral	400 Mg, Qd	Sanofi
Darunavir	S	Oral	800 Mg, Qd	Not Reported
Ritonavir Sandoz	S	Oral	100 Mg, Qd	Not Reported
Folifill	C			Not Reported
Eutirox	C			Not Reported
Ceftriaxone	C		1 Df, Qd	Not Reported
Lasix [Furosemide]	C			Not Reported
Urbason [Methylprednisolone]	C	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Omeprazole	C			Not Reported
Trelegy Ellipta	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593767			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphthous Ulcer; Drug Ineffective; Intentional Product Use Issue; Mouth Ulceration; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759960	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592727		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event;	Actemra			S	Unknown			Not Reported
Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability;	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported

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Knee Arthroplasty; Lip	Humira	S	Subcutaneous	Not Reported
Ulceration; Mobility	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Decreased; Mouth	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Ulceration;	Orencia	S	Unknown	Not Reported
Musculoskeletal Disorder;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Skin Warm; Spinal	Simponi	S	Subcutaneous	Not Reported
Stenosis; Therapeutic	Gold	C		Not Reported
Product Effect Decreased;	Methotrexate	C	Subcutaneous	Not Reported
Urinary Tract Infection	Prednisone	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17759962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594885		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Intolerance; Neoplasm	Apo-Azathioprine			S	Unknown			Not Reported
Malignant; Non-Hodgkin'S	Arava			S	Unknown			Not Reported
Lymphoma	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760008	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594033			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760032	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593250		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Adverse Drug Reaction; Alopecia; Anticipatory Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Synovitis	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Acetaminophen	C		Not Reported
	Cetirizine Hydrochloride	C		Not Reported
	Desoximetasone	C		Not Reported
	Dexamethasone	C		Not Reported
	Gabapentin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760116	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Measured Potency Issue; Therapy Non-Responder	Hydroxychloroquine Sulfate			S				Dr Reddys

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760294	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA116702		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S				Sanofi
	Enoxaparin Sodium			S	Subcutaneous	60 Mg, Q12h		Sanofi

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Dexamethasone	S	Intravenous (not otherwise specified)	20 Mg, Qd For 6 Days Followed By 10 Mg Day X 5 Days	Not Reported
Dexamethasone	S			Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Azithromycin	S			Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, 1x	Not Reported
Tocilizumab	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760385	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02050		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cornea Verticillata; Off Label Use	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Lupin	
	Hydroxychloroquine			S	Unknown	1200 Milligram (21.9 Mg/Kg) High Dose		Lupin	
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported	
	Everolimus			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760413	EXPEDITED (15-DAY)		DE, OT	ES-VELOXIS PHARMACEUTICALS- 2020VELES-000434		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Envarsus			S	Oral	Unk		Chiesi	
	Lopinavir + Ritonavir			S	Oral	2 Df, Q12h		Not Reported	
	Azitromicina			S	Oral	500 Milligram, Qd		Not Reported	
	Hidroxiclороquina Sulfato			S	Oral	200 Milligram, Qd		Not Reported	
	Levofloxacin [Levofloxacin]			S	Endocervical	Unk		Not Reported	
	Prednisona			C	Oral	20 Milligram, Qd		Not Reported	
	Ceftriaxona [Ceftriaxone]			C	Endocervical	Unk		Not Reported	

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Enoxaparina Sodica

C

Subcutaneous

40 Milligram, Qd

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760655	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594303			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760679	EXPEDITED (15-DAY)		OT	NVSC2020DE122948			Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Off Label Use; Respiratory Tract Infection; Vomiting	Methotrexate			S	Unknown			Novartis	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Abatacept			S	Unknown			Not Reported	
	Roactemra			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760691	EXPEDITED (15-DAY)		DS	CA-ROCHE-2590101		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Indocid [Indometacin]			S	Unknown			Not Reported	
	Indometacin			S	Unknown			Not Reported	
	Indomethacin [Indometacin]			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Remicade			S	Intravenous (not			Not Reported	

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		otherwise specified)	
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Gold	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Cymbalta	C	Oral	Not Reported
Folic Acid	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17760787	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2020M1044962		70 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594942			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Simponi			C				Not Reported
	Methotrexate			C				Not Reported

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08-May-2020	17761128	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1231758		50 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder	Hydroxychloroquine Sulphate Bp 200mg Tablet			S	Oral	200 Mg; 15.4. In The Evening And 16.4. In The Morning 400 Mg, Then 200 Mg/12 H		Teva	
	Daleron 500 Mg			S	Oral	500 Mg; As Necessary, Dotal Dose Of 2 Tbl On 14. And 15.4.		Not Reported	
	Fragmin 5000 Ie			S	Subcutaneous	5000iu; 5000/24 Ur		Not Reported	
	Pantoprazol Teva 20 Mg			C	Oral	20 Milligram Daily;		Not Reported	
	Folkodin Alkaloid-Int			C	Oral	10 Mg; As Necessary 2caps/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761229	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591156		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Naproxen			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

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Xeljanz			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761316	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231938			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bursitis; Chronic Obstructive Pulmonary Disease; Drug Hypersensitivity; Gastrectomy; Hypothyroidism; Mammoplasty; Obesity; Osteoarthritis; Osteopenia; Phlebectomy; Synovitis; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Leflunomide			S	Unknown	10 Milligram Daily;		Barr	
	Cosentyx			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	N-(3-Chloroallyl)Hexaminium Chloride			S	Unknown			Not Reported	
	Penicillin G			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Stelara			S	Unknown			Not Reported	
	Stelara			S	Unknown			Not Reported	
	Cetirizine			C		20 Milligram Daily;		Not Reported	
	Enbrel			C				Not Reported	
	Lasix			C				Not Reported	
	Montelukast			C		10 Milligram Daily;		Not Reported	
	Synthroid			C		75 Microgram Daily;		Not Reported	
	Terbutaline Sulfate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761320	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1044981		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Venlafaxine			S	Oral	225 Milligram, Qd		Not Reported	
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan	
	Loxapine			S	Oral	155 Milligram, Qd		Mylan	

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Theralene	S	Oral	50 Milligram, Qd	Mylan
Paracetamol	C	Oral	1 Gram, Qd	Mylan
Nicopatch	C	Transdermal	7 Milligram, Qd	Mylan
Diazepam	C	Oral	10 Milligram, Qd	Mylan
Atorvastatine /01326101/	C	Oral	40 Milligram, Qd	Mylan
Nicotine	C	Oral	12 Milligram, Qd	Mylan
Macrogol 4000	C	Oral	Unk	Mylan
Nebivolol	C	Oral	7.5 Milligram, Qd	Mylan
Zopiclone	C	Oral	7.5 Milligram, Qd	Mylan
Ramipril	C	Oral	1.25 Milligram, Qd	Mylan
Akineton /00079502/	C	Oral	4 Milligram, Qminute	Mylan
Ezetimibe	C	Oral	10 Milligram, Qd	Mylan
Kardegic	C	Oral	75 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761340	EXPEDITED (15-DAY)		HO, OT	PT-ADVANS PHARMA-GSH201712-006713			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Response Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisolone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	25 Mg, Qd		Not Reported
	Methylprednisolone			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			C	Unknown	2 G, Qd		Not Reported
	Cyclophosphamide			C	Unknown	Unk		Not Reported
	Azathioprine			C	Intracardiac	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761350	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232520		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Naproxen	S	Unknown	1000 Milligram Daily;	Not Reported
	Methotrexate	S	Subcutaneous		Barr
	Celebrex	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761415	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232499		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthropathy; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Polyarthrititis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Naproxen			S	Unknown			Teva
	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
Triamcinolone	S	Other		Not Reported
Sulfasalazine	S	Oral	250 Milligram Daily;	Not Reported
Triamcinolone Hexacetonide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761416	EXPEDITED (15-DAY)	HO		CA-TEVA-2020-CA-1232985		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Naproxen Sodium			S	Unknown			Teva
Arthropathy; Body Height	Prednisone			S	Unknown			Actavis
Below Normal; Bone	Methotrexate			S	Unknown			Barr
Density Decreased; C-	Actemra			S	Intravenous (not			Not Reported
Reactive Protein					otherwise specified)			
Increased; Condition	Actemra			S	Intravenous (not			Not Reported
Aggravated; Diarrhoea;					otherwise specified)			
Dizziness; Drug								
Ineffective; Drug	Anakinra			S	Subcutaneous	50 Milligram Daily;		Not Reported
Intolerance; Drug Specific	Anakinra			S	Unknown	50 Milligram Daily;		Not Reported
Antibody; Human	Enbrel			S	Unknown			Not Reported
Antichimeric Antibody	Humira			S	Subcutaneous			Not Reported
Positive; Juvenile	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Idiopathic Arthritis; Mobility	Immune Globulin (Human)			S	Intravenous (not			Not Reported
Decreased; Nausea;					otherwise specified)			
Obesity; Polyarthritis;	Infliximab			S	Intravenous (not			Not Reported
Psoriasis; Red Blood Cell					otherwise specified)			
Sedimentation Rate								
Increased; Septic Shock;	Orencia			S	Intravenous (not			Not Reported
Synovitis; Vomiting					otherwise specified)			
	Prednisone			S	Oral	2.6 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	250 Milligram Daily;		Not Reported
	Triamcinolone			S	Other			Not Reported
	Triamcinolone Hexacetonide			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761468	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232206		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Laboratory Test Abnormal	Leflunomide			S	Unknown	20 Milligram Daily;		Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Hyzaar			C	Unknown			Not Reported	
	Venlafaxine Hydrochloride			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761493	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2020-CA-1232500		12 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present; Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia;	Naproxen			S	Unknown	100 Milligram Daily;		Teva	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Oral			Actavis	
	Prednisone			S	Unknown			Actavis	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypokalaemia; Hypotension; Immunodeficiency; Impaired Quality Of Life; Joint Destruction; Joint Effusion; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Prescribed Underdose; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Actemra	S	otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Anakinra	S	Subcutaneous	50 Milligram Daily;	Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Naproxen	S	Oral	6 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral	2.6 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral	10 Milligram Daily;	Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	5 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported
	Immune Globulin(Human)	S	Intravenous (not otherwise specified)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Immune Globulin(Human)	S	Intravenous (not otherwise specified)	Not Reported
Immune Globulin(Human)	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Oral 2.6 Milligram Daily;	Not Reported
Prednisone	S	Oral 6 Milligram Daily;	Not Reported
Prednisone	S	Oral 2.6 Milligram Daily;	Not Reported
Sulfasalazine	S	Oral 250 Milligram Daily;	Not Reported
Sulfasalazine	S		Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
Tocilizumab	S		Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Hexacetonide	S	Other	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported
	Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761502	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1045105		62 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hepatitis; Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan
	Ceftriaxona /00672201/			S				Mylan
	Dolquine			S	Oral	400 Mg Dia		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761537	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1231771			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Methotrexate			S	Unknown			Barr
	Leflunomide			S	Unknown			Barr
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Otezla			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Advair			C				Not Reported
	Allopurinol			C				Not Reported
	Atrovent Hfa			C				Not Reported

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Codeine	C	Not Reported
Cyclobenzaprine Hydrochloride	C	Not Reported
Dilaudid	C	Not Reported
Esomeprazole Magnesium Trihydrate	C	Not Reported
Hydromorphone Hydrochloride	C	Not Reported
Hydroxychloroquine Sulfate	C	Not Reported
Ibuprofen	C	Not Reported
Leucovorin Calcium	C	Not Reported
Sulfasalazine	C	Not Reported
Ventolin Hfa	C	Not Reported
Xeljanz	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761541	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2020-CA-1231733		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Rheumatoid Factor Positive; Sepsis; Synovitis; Terminal State; Thrombosis	Leflunomide Doxycycline Hyclate Methotrexate Actemra Enbrel Humira Humira Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Orencia Remicade Remicade Rituximab Rituximab Rituximab Rituximab			S S S S S S S S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Intravenous (not	10 Milligram Daily;		Barr Actavis Barr Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)	
Rituximab	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Rituximab;Urelumab	C	Unknown		Not Reported
Simponi	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761575	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045111		53 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Sedacion		Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Dolquine			S				Mylan
	Dexametasona /00016001/			C	Intravenous (not otherwise specified)	4 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761605	EXPEDITED (15-DAY)		LT, OT	CA-TEVA-2020-CA-1233076			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic	Naproxen Sodium			S	Unknown			Teva
	Indomethacin			S	Unknown			Actavis

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Product Effect Decreased; Visual Impairment	Actemra	S	Unknown		Not Reported
	Celebrex	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761786	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2020M1046273		39 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Methotrexate			S	Unknown	10 Milligram, Qw		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Mylan	
	Triamcinolone Acetonide			S		Intralesional Injection		Mylan	
	Isoniazid			C	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17761846	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1045048		17 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cryptococcosis; Hepatitis Toxic; Off Label Use	Methotrexate			S	Unknown	Unk		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	750 Milligram/Sq. Meter, Q2w		Mylan	
	Prednisolone			S	Unknown	Unk		Mylan	
	Prednisolone			S	Unknown	Unk		Mylan	
	Prednisolone			S	Unknown	Unk		Mylan	
	Cellcept /01275102/			S	Unknown	0.5 Gram, Qd		Mylan	
	Cellcept /01275102/			S	Unknown	2 Gram, Qd		Mylan	
	Methylprednisolone			S	Unknown	Unk		Mylan	

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Hydroxychloroquine			S	Unknown	Unk	Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17762248	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1233084		52 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Drug Ineffective	Naproxen			S	Unknown			Teva	
	Methotrexate			S	Subcutaneous			Barr	
	Metoprolol			S	Unknown			Actavis	
	Prednisone			S	Unknown			Actavis	
	Apo-Metoprolol			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Naproxen Sodium			C	Unknown			Not Reported	
	Rosuvastatin Calcium			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17762464	EXPEDITED (15-DAY)	HO		CA-TEVA-2020-CA-1232561		33 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anxiety; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Dysbiosis; Fatigue; Infection; Inflammation; Insomnia; Maternal Exposure During Pregnancy; Nausea; Pain; Psoriasis; Rheumatoid Factor Positive; Synovitis; Thyroid Disorder	Naproxen	S	Unknown	1500 Milligram Daily;	Teva
	Naproxen	S		1500 Milligram Daily;	Teva
	Methotrexate	S	Subcutaneous		Barr
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Penicillin	S	Unknown		Not Reported
	Plaquenil	C			Not Reported
	Synthroid	C			Not Reported
	Tramadol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17762507	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594982		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	7.0 Years		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17762702	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020185605		47 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis Acute; Off Label	Azithromycin			S	Oral	500 Mg, Daily		Pfizer

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Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin	S				Pfizer
	Dexketoprofen	S	Intravenous (not otherwise specified)	25 Mg, Every 8 Hours		Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Daily		Not Reported
	Hydroxychloroquine	S				Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab	S				Not Reported
	Tocilizumab Paracetamol	S S	Oral	1 G, Every 8 Hours		Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17762783	EXPEDITED (15-DAY)		HO, LT, OT	JP- OSMOTICA_PHARMAC EUTICAL_US_LLC- POI0573202000331		41 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Haemorrhage; Hormone Level Abnormal; Hypogonadism; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Uterine Obstruction	Divigel			S	Transdermal	1.44 To 2.88 Mg Every 2 Days Each Between Fet 1 And Fet 4		Osmotica
	Divigel			S	Transdermal	1.44 Mg Every 2 Days During Fet 5		Osmotica
	Divigel			S	Oral	1.5 To 3.0 Mg Per Day During Fet 5		Osmotica
	Tacrolimus Monohydrate			S				Not Reported
	Progesterone			S	Vaginal			Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17763134	EXPEDITED (15-DAY)		DE	CN-FRESENIUS KABI- FK202004535		37 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Histoplasmosis	Methylprednisolone			S	Unknown			Fresenius Medical

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disseminated; Respiratory Failure	(Manufacturer Unknown) Methylprednisolone (Manufacturer Unknown) Prednisone Hydroxychloroquine Hydroxychloroquine	S S S S	Unknown Oral Unknown Oral	Unknown	Care Fresenius Medical Care Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17763193	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1232108		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy;	Leflunomide			S	Oral	20 Milligram Daily;		Barr
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actonel			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Actonel			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown	300 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown 300 Milligram Daily;	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Oral 10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17763198	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232213		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Naproxen Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17763247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594680		24 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Rituximab			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Elavil [Amitriptyline Hydrochloride]			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Medroxyprogesterone Acetate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Naprosyn [Naproxen]			S	Unknown			Not Reported	
	Oxycodone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Amitriptyline			S	Unknown			Not Reported	
	Cyclosporine			C				Not Reported	
	Depo Provera			C	Intramuscular	Sterile Aqueous Suspension		Not Reported	
	Kineret			C	Subcutaneous	100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17765180	DIRECT	Y	DE			58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sars-Cov-2 Test Positive	Hydroxychloroquine Sulfate Tablet			S	Oral			Actavis	
	Lorazepam			C				Not Reported	

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Morphine	C	Not Reported
Sodium Chloride 0.9%	C	Not Reported
Cefepime	C	Not Reported
Calcium Gluconate	C	Not Reported
Norepinephrine	C	Not Reported
Propofol	C	Not Reported
Zosyn	C	Not Reported
Azithromycin	C	Not Reported
Venofer	C	Not Reported
Kphos	C	Not Reported
D5w	C	Not Reported
1/2ns	C	Not Reported
Acetaminophen	C	Not Reported
Acetylcysteine	C	Not Reported
Ascorbic Acid	C	Not Reported
Bumetanide	C	Not Reported
Benadryl	C	Not Reported
Enoxaparin	C	Not Reported
Insulin Regular	C	Not Reported
Magnesium Hydroxide	C	Not Reported
Propofol	C	Not Reported
Reglan	C	Not Reported
Zofran	C	Not Reported
Versed	C	Not Reported
Protonix	C	Not Reported
Kayexalate	C	Not Reported
Zinc	C	Not Reported
Succinylcholine	C	Not Reported
Etomidate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2020	17765469	DIRECT	N	OT			63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Cell Carcinoma	Humira Cf 40mg			S	Subcutaneous	Other Frequency:Once Every;		Abbvie
	Sulfasalazin			C				Not Reported
	Acyclovir			C				Not Reported
	Armour Thyro			C				Not Reported
	Gabapentin			C				Not Reported

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	Hydroxychlor Pilocarpine			S C				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	11610346	EXPEDITED (15-DAY)		HO	CA-ROCHE-1643242		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Neoplasm; Decreased Immune Responsiveness; Immune System Disorder; Lyme Disease	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	13303877	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1902159		42 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Disability; Drug Ineffective; Gastrointestinal Disorder; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
Humira			S	Subcutaneous			Not Reported		

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Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	15344061	EXPEDITED (15-DAY)		OT	CA-ROCHE-2177451		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17240286	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514006		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Bronchitis Chronic; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Surgical Failure; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine]			S	Unknown			Not Reported

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Sulfate] Remicade	S	Intravenous (not otherwise specified)	Not Reported
Mobicox	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17287257	EXPEDITED (15-DAY)	HO		CA-ROCHE-2520375		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Clostridium	Actemra			S	Unknown			Not Reported
Difficile Infection;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contusion; Dehydration;								
Diabetes Mellitus; Drug	Apo-Prednisone			S	Unknown			Not Reported
Hypersensitivity; Drug	Warfarin			S	Unknown			Not Reported
Ineffective; Dysphonia;	Warfarin			S	Unknown			Not Reported
Gait Disturbance;								
Hospitalisation; Joint	Arava			S	Unknown			Not Reported
Swelling; Loss Of	Enbrel			S	Unknown			Not Reported
Consciousness;	Humira			S	Subcutaneous			Not Reported
Nasopharyngitis;	Hydroxychloroquine			S	Unknown			Not Reported
Oropharyngeal Pain; Pain;	Methotrexate			S	Unknown			Not Reported
Productive Cough;	Methotrexate			S	Unknown			Not Reported
Rheumatoid Arthritis;	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Secretion Discharge;	Sulfate]							
Sputum Discoloured;	Prednisone			S	Unknown			Not Reported
Therapeutic Product Effect	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Decreased; Thrombosis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17420209	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543007		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Alopecia; Anxiety; Arthralgia; Asthenia; Contraindicated Product Administered; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder; Malaise; Nausea; Pain; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	3 Years		Not Reported	
	Humira			S	Subcutaneous	3 Months		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Methotrexate			S	Unknown	9.0 Years		Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Gabapentin			C	Unknown			Not Reported	
	Reactine [Cetirizine Hydrochloride]			C	Unknown			Not Reported	
	Cetirizine Hydrochloride			C	Unknown			Not Reported	
	Desoximetasone			C				Not Reported	
	Dexamethasone			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17655678	EXPEDITED (15-DAY)		DE, LT	FR-TEVA-2020-FR-1221608		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Ventricular Tachycardia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported	
	Lasilix 20 Mg/2 ML, Solution Injectable En Ampoule			S	Intravenous (not otherwise specified)	2 Dosage Forms		Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Sufentanil			C	Intravenous (not otherwise specified)			Not Reported	
	Perfalgan 10 Mg/ML, Solution Pour Perfusion			C	Intravenous (not otherwise specified)			Not Reported	
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)			Not Reported	
	Midazolam			C	Intravenous (not otherwise specified)			Not Reported	
	Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion			C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported	
	Transipeg			C	Oral			Not Reported	
	Potassium (Chlorure De)			C	Intravenous (not otherwise specified)			Not Reported	
	Nimbex			C	Intravenous (not otherwise specified)			Not Reported	
	Effexor L.P. 37,5 Mg, Gelule A Liberation Prolongee			C	Oral			Not Reported	
	Ultibro Breezhaler			C	Respiratory (inhalation)			Not Reported	
	Seresta 10 Mg, Comprime			C	Oral			Not Reported	
	Rocephine			C	Intravenous (not otherwise specified)			Not Reported	

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09-May-2020	17705027	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202004003546			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury; Off Label Use; Pulmonary Embolism	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia	
	Paracetamol			C		Unk		Not Reported	
	Rocephine			C		Unk		Not Reported	
	Spiramycine			C		Unk		Not Reported	
	Enoxaparin			C		Unk		Not Reported	
	Dexamethasone			C		Unk		Not Reported	
	Cefepime			C		Unk		Not Reported	
	Cefazolin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17760306	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231595		49 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Forms		Not Reported	
	Lopinavir/Ritonavir			S	Oral	4 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17762677	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594827			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis;	Rituxan			S	Intravenous drip			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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White Blood Cell Count Decreased	Hydroxychloroquine Sulfate	S	Unknown	Therapy Duration: 7.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	C	Subcutaneous		Not Reported
	Xeljanz	C			Not Reported
	Arava	C			Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17762926	EXPEDITED (15-DAY)		HO, LT, OT	JP-STRIDES ARCOLAB LIMITED-2020SP005498		41 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Disorder; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Off Label Use; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Tacrolimus			S	Unknown	4 Milligram		Strides
	Prednisolone			S	Unknown	7.5 Milligram		Not Reported
	Prednisolone			S	Unknown	Dose Increased		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram		Not Reported
	Estradiol			S	Transdermal	Unk		Not Reported
	Progesterone			S	Vaginal	300 Milligram (Vaginal Tablet)		Not Reported
	Dydrogesterone			S	Oral	15 Milligram Per Day		Not Reported
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported
	Oxytocin			S	Unknown	Unk		Not Reported

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09-May-2020	17763267	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594042		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Off Label Use; Pyrexia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763305	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592057		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Migraine; Nausea; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intracavernous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594865		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Stress	Rituxan			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	7.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763309	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594899		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763311	EXPEDITED (15-DAY)		DS	CA-ROCHE-2595012		48 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Naproxen			C	Unknown			Not Reported	
	Levothyroxine Sodium			C	Unknown			Not Reported	
	Bupropion			C	Unknown			Not Reported	

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		Esomeprazole	C	Unknown				Not Reported	
		Folic Acid	C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763349	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232236		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763356	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232701		51 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763364	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056-3397056-00		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Right	Kaletra 200/50			S	Oral	Comprimé Pelliculé		Not Reported	
	Plaquenil			S	Oral	200 Mg, Comprimé Enrobé		Not Reported	
	Amlodipine			C				Not Reported	
	Alprazolam			C				Not Reported	

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		Lovenox		C					Not Reported
		Paracetamol		C					Not Reported
		Candesartan Cilexetil		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763369	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1232936		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Pancreatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Metilprednisolona (888a)			S	Intravenous (not otherwise specified)	250 Mg		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	560 Mg		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	200 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763370	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232934		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Enoxaparina			S	Subcutaneous	40 Mg		Not Reported	
	Enoxaparina			S	Subcutaneous	60 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763372	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594953			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Drug Intolerance; Nausea	Rituxan	S	Intravenous drip	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763378	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594210		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Drug Ineffective; Hypersensitivity; Laryngeal Disorder; Nausea; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763390	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591044			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Folic Acid	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763394	EXPEDITED (15-DAY)	HO		ES-TEVA-2020-ES-1232235		79 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Colchicina / Dicloverina			S	Oral	1 Dosage Forms		Not Reported
	Colchicina / Dicloverina			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763429	EXPEDITED (15-DAY)	OT		CA-ROCHE-2594157		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatotoxicity; Nausea; Neoplasm Malignant; Rheumatoid Arthritis; Thyroid Neoplasm	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported

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Celebrex	S		Not Reported
Enbrel	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594901			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; No Adverse Event; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported

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	Prednisone	C	Oral	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763447	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595032		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763468	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056- 3397060-00		92 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qt Prolonged; Electrocardiogram U- Wave Prominent	Kaletra 200/50			S	Oral	Comprimé Pelliculé		Not Reported
	Kaletra			S	Oral	80 Mg/20 Mg, Solution Buvable		Not Reported
	Cordarone			S	Oral	200 Mg, Comprimé Sécable		Not Reported
	Plaquenil			S	Oral			Not Reported
	Xarelto			C				Not Reported
	Levothyrox			C				Not Reported
	Xatral			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763470	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1231930		56 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva	
	Hidroxicloroquina (2143a)			S	Oral	2 Comp Cada 12 Horas El Primer Día Y Posteriormente 2 Comp Cada 24 H,		Teva	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763487	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232707		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Completed Suicide	Hidroxicloroquina (2143a)			S	Oral	Loading Dose: 400 / 12h And Then 200mg / 12h Unit Dose :200 Milligram		Teva	
	Metoclopramida (1958a)			C	Intravenous (not otherwise specified)	10 Milligram		Not Reported	
	Metamizol (111a)			C	Intravenous (not otherwise specified)	2 Gram		Not Reported	
	Paracetamol (12a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Ipratropio (1067a)			C	Oral	20 Microgram		Not Reported	
	Ceftriaxona (501a)			C		2 Gram		Not Reported	
	Beclometasona (463a)			C	Respiratory (inhalation)			Not Reported	
	Furosemida (1615a)			C	Intravenous (not otherwise specified)	20 Milligram		Not Reported	

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Azitromicina (7019a)	C	Oral	500 Mg On The First Day Unit Dose :250 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763509	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232933		78 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported
	Propofol			S	Unknown			Not Reported
	Propofol			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos			S	Oral	A Compressed Breakfast And Dinner 200 Milligram		Not Reported
	Midazolam (2256a)			S	Unknown			Not Reported
	Midazolam (2256a)			S				Not Reported
	Kaletra			S	Oral			Not Reported
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprimido			C				Not Reported
	Rilast Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo Pa			C				Not Reported
	Omnice Ocas 0,4 Mg Comprimidos De Liberacion Prolongada Recubiertos Con			C				Not Reported
	Simvastatina 20 Mg 28 Comprimidos			C				Not Reported
	Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimidos (			C				Not Reported
	Cortic - Corticoide			C	Unknown	Low Dose Corticoids		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763514	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1232632		74 YR	Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged	Propranolol			S	Oral			Actavis	
	Laroxyl 40 Mg/MI, Solution Buvable			S	Oral	15 Gtt		Not Reported	
	Zithromax 250 Mg, Comprime Pellicule			S	Oral	500 Milligram		Not Reported	
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	400 Milligram		Not Reported	
	Paracetamol			C	Oral	If Necessary		Not Reported	
	Pantoprazole			C	Oral	20 Milligram		Not Reported	
	Oxygene			C	Respiratory (inhalation)	1 Liters		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763517	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232553		57 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763537	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232935		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia	Amoxicilina / Acido Clavulanico			S	Intravenous (not otherwise specified)	1 Gr /8h		Teva	
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva	
	Hidroxicloroquina (2143a)			S				Teva	

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Enoxaparina (2482a)	S	Subcutaneous	80 Mg Day	Not Reported
Ceftazidima (189a)	S	Intravenous (not otherwise specified)	2gr/8h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763552	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232937		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Enoxaparina (2482a)			S	Subcutaneous	120 Milligram Daily; Unit Dose: 60 Mg		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a) Dexametasona (722a)			S S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Not Reported Not Reported
	Dexametasona (722a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763555	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232242		79 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763557	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232550		64 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Levofloxacinо (2791a)			S	Oral	500 Milligram Daily;		Teva	
	Roactemra 20 Mg/MI, Concentrado Para Solucion Para Perfusion			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763558	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232237		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763559	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232931		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Cardio-Respiratory Arrest	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Kaletra 200/50 Mg Comprimidоs Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; Unit Dose: 2 Df		Not Reported	
	Kaletra 200/50 Mg Comprimidоs Recubiertos Con Pelicula , 120			S				Not Reported	

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Comprimid Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763644	EXPEDITED (15-DAY)	DE		ES-TEVA-2020-ES-1232241		84 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Hidroxiclороquina (2143a)			S	Oral	400 Mg Loading Dose Followed By 200 Mg / Day, 200 Mg		Teva	
	Azitromicina (7019a)			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	12958296	EXPEDITED (15-DAY)	OT		CA-ROCHE-1627311		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic Enzyme Increased; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomycosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	2 Doses		Not Reported	
	Prednisone			S	Oral			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous	Therapy Duration: 12 Months		Not Reported	
	Orencia			S	Unknown	Therapy Duration: 7 Years		Not Reported	
	Humira			S	Subcutaneous	Therapy Duration: 4 Months		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 9		Not Reported	

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Simponi	S	otherwise specified)	Months	
Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Cimzia	S	Unknown		Not Reported
Hydroxychloroquine	S	Subcutaneous		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	17721515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589898			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Ineffective;	Tocilizumab			S	Unknown			Not Reported
Goitre; Headache;	Tocilizumab			S	Unknown			Not Reported
Inflammation; Joint	Rituximab			S	Intravenous drip			Not Reported
Swelling; Knee	Apo-Prednisone			S	Oral			Not Reported
Arthroplasty; Lower	Apo-Prednisone			S	Oral			Not Reported
Respiratory Tract	Enbrel			S	Subcutaneous			Not Reported
Infection; Musculoskeletal	Hydroxychloroquine			S	Unknown			Not Reported
Pain; Musculoskeletal	Methotrexate			S	Unknown			Not Reported
Stiffness; Nasopharyngitis;	Methotrexate			S	Oral			Not Reported
Nephrolithiasis; Pain; Pain	Orencia			S	Intravenous (not			Not Reported
In Extremity; Peripheral					otherwise specified)			
Swelling; Rheumatoid	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported
Arthritis; Swelling	Sulfate]							
	Remicade			S	Intravenous (not			Not Reported
					otherwise specified)			
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	17763679	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS- 050282			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Risperidone			S	Oral	2 Milligram, Qd		Zydus Pharm
	Plaquenil Sulfate			S	Oral	600 Milligram, Qd		Not Reported
	Effexor			S	Oral	150 Milligram, Qd		Not Reported
	Acebutolol			C	Oral	400 Milligram		Not Reported
	Oxazepam			C	Oral	100 Milligram		Not Reported
	Enoxaparine Sodique			C	Subcutaneous	4000 International Unit		Not Reported
	Macrogol 4000			C	Oral	2 Dosage Form		Not Reported
	Amlodipine			C	Oral	10 Milligram		Not Reported
	Zopiclone			C	Oral	7.5 Milligram		Not Reported
	Nicardipine			C	Oral	60 Milligram		Not Reported
	Hydrochlorothiazide			C	Oral	25 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	17763813	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595003		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gingival Bleeding; Headache;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection; Joint Swelling; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Peripheral Swelling; Rash; Syncope; Urticaria	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prevacid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	17763889	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1233080			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling;	Naproxen			S	Unknown			Teva	
Musculoskeletal Pain;	Methotrexate			S	Unknown			Barr	
Musculoskeletal Stiffness; Nausea; Pain In Extremity;	Azathioprine			S	Unknown			Not Reported	
Peripheral Swelling;	Metoprolol			S	Unknown			Actavis	
Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Pms-Azithromycin			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	17763895	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1232981		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Joint Laxity; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Naproxen Sodium			S	Unknown			Teva
	Prednisone Acetate			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Folic Acid			C	Subcutaneous			Not Reported
	Leflunomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2020	17763913	EXPEDITED (15-DAY)		DS	CA-ROCHE-2594699		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	12470327	EXPEDITED (15-DAY)		OT	CA-ROCHE-1776829		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown	Every 1 Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	13111555	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878349		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Herpes Zoster; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Darifenacin	C		Not Reported
Arava	C		Not Reported
Ativan	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Cortisone	C	Oral	Not Reported
Dilaudid	C		Not Reported
Darifenacin	C	Unknown	Not Reported
Loperamide	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C	Unknown	Not Reported
Pantoprazole Sodium	C		Not Reported
Plantago Ovata	C		Not Reported
Synthroid	C		Not Reported
Vagifem	C	Vaginal	Not Reported
Diphenhydramine	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Desoximetasone	C	Oral	Not Reported
Furosemide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	13116772	EXPEDITED (15-DAY)		OT	CA-ROCHE-1878330		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Chills; Drug Ineffective; Drug Intolerance; Headache; Hepatic Enzyme Increased; Joint Swelling; Liver Disorder; Mesenteritis; Nausea; Oedema Peripheral; Pyrexia	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported

FDA Adverse Event Reporting System

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Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	14222162	EXPEDITED (15-DAY)		OT	CA-ROCHE-2026226			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	14411605	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP005230		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Eye Disorder; Gait Inability; Joint Dislocation; Stomatitis	Diclofenac Sodium			S	Unknown	Unk		Apotex
	Desoximetasone			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	14682212	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1017484			Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apgar Score Low; Foetal	Prednisone			S	Transplacental	25 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During Pregnancy; Low Birth Weight Baby; Neonatal Respiratory Distress Syndrome; Premature Baby	Prednisone	S	Transplacental	7.5 Mg, Qd	Not Reported
	Prednisone	S	Transplacental	10 Mg, Qd	Not Reported
	Hydroxychloroquine	S	Transplacental	400 Mg, Qd	Not Reported
	Acetylsalicylic Acid	S	Transplacental	100 Mg, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	15263425	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167406			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)	Cyclical		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	15408169	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20180908328		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Disability; Drug Ineffective; Joint Stiffness; Joint Swelling; Limb Deformity; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indomethacin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapeutic Product Effect Decreased; Treatment Failure	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Actemra	S	Unknown	Not Reported
	Radioactive Gold	S	Unknown	Not Reported
	Indocid /00003801/	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Cymbalta	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	15458116	EXPEDITED (15-DAY)		OT	CA-ROCHE-2192139		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Extended Release Tablet Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	15741776	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC- 20181218371		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Erosion; Bronchiectasis; Chest Pain; Disease	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
Susceptibility; Drug	Remicade			S				Not Reported	
Ineffective; Epicondylitis; Joint Swelling; Myocardial	Simponi			S	Subcutaneous			Janssen	
Infarction; Pulmonary	Enbrel			S	Unknown			Not Reported	
Fibrosis; Therapeutic	Enbrel			S				Not Reported	
Product Effect Decreased;	Arava			S	Oral			Not Reported	

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Toxicity To Various Agents; Upper Limb Fracture	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S		Not Reported
	Procytox	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Neoral	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	16387989	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-029731			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac Potassium			S	Oral	75 Milligram		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk, Two Times A Day		Not Reported
	Depo-Medrol			C	Intramuscular	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	16522648	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177990			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Contraindicated Product Administered; Pain; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	Unk		Sanofi
	Methotrexate			S	Oral	Unk Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Enbrel			S	Unknown	1000 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	16524371	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177768			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Encephalitis; Hypoaesthesia	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Pregabalin			C	Oral	50 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	16530361	EXPEDITED (15-DAY)		OT	CA-SA-2019SA177463			Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Pain; Rash; Squamous Cell Carcinoma; Treatment Failure	Hydroxychloroquine			S	Oral			Sanofi
	Arava			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Citalopram Hydrobromide			C		40 Mg		Not Reported
	Prednisone			C		10 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17149990	EXPEDITED (15-DAY)		OT	FR-ACCORD-165350		57 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antinuclear Antibody Positive; Bicytopenia; Dermatitis Psoriasiform; Dna Antibody; Drug Ineffective; Evans Syndrome; General Physical Health Deterioration; Hypergammaglobulinaemi a; Lymphadenopathy; Off Label Use; Pericarditis; Pyrexia; Scar; Skin Lesion; Subacute Cutaneous Lupus Erythematosis; Systemic Lupus Erythematosis	Methotrexate			S	Unknown			Accord
	Mycophenolic Acid			S				Accord
	Hydroxychloroquine			S	Unknown			Not Reported
	Omeprazole			S				Not Reported
	Prednisone			S				Not Reported
	Azathioprine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17195982	EXPEDITED (15-DAY)		OT	CA-ROCHE-2498563			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Contraindicated Product	Actemra	S	Unknown	Not Reported
Administered; Drug	Enbrel	S	Subcutaneous	Not Reported
Ineffective; Drug	Enbrel	S	Unknown	Not Reported
Intolerance; Headache;	Humira	S	Subcutaneous	Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown	Not Reported
Tremor	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17246962	EXPEDITED (15-DAY)		HO	CA-ROCHE-2514284		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Blood	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
Magnesium Increased; Blood Potassium	Celebrex			S	Oral			Not Reported	

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Increased; Cyst; Deafness	Enbrel	S	Unknown	Not Reported
Neurosensory; Diarrhoea;	Fentanyl	S	Unknown	Not Reported
Drug Ineffective; Drug	Gabapentin	S	Oral	Not Reported
Intolerance; Dry Eye;	Methotrexate	S	Subcutaneous	Not Reported
Epigastric Discomfort;	Myochrysine	S	Intramuscular	Not Reported
Fatigue; Gastrointestinal	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Disorder; Infection;	Oxycontin	S	Unknown	Not Reported
Nausea; Osteoarthritis;	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Osteopenia; Pleural	Sulfasalazine	S	Unknown	Not Reported
Fibrosis; Pleural	Nasonex	C	Unknown	Not Reported
Thickening; Presbycusis;	Prednisone	C	Unknown	Not Reported
Renal Impairment; Skin	Trazodone	C	Unknown	Not Reported
Lesion; Sleep Disorder;	Zoledronic Acid	C	Unknown	Not Reported
Treatment Failure	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17310017	EXPEDITED (15-DAY)		OT	CA-ROCHE-2527625		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Actemra			S	Unknown			Not Reported
Arthralgia; Arthropathy;	Arava			S	Unknown			Not Reported
Back Pain; Condition	Enbrel			S	Unknown			Not Reported
Aggravated;	Humira			S	Unknown			Not Reported
Contraindicated Product	Humira			S	Subcutaneous			Not Reported
Administered; Drug	Humira			S	Subcutaneous			Not Reported
Ineffective; Fatigue; Joint	Humira			S	Subcutaneous			Not Reported
Swelling; Loss Of	Humira			S	Subcutaneous			Not Reported
Personal Independence In	Humira			S	Subcutaneous			Not Reported
Daily Activities; Pain;								

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Peripheral Swelling; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17433987	EXPEDITED (15-DAY)		OT	CA-ROCHE-2551545		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Contraindicated Product Administered; Depression; Diarrhoea; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Musculoskeletal Disorder; Rheumatoid Arthritis; Sleep Disorder	Rituxan			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17477145	EXPEDITED (15-DAY)		OT	CA-ROCHE-2559556		41 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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Treatment Failure	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17683228	EXPEDITED (15-DAY)		DE, OT	FR-ADVANSZ PHARMA-202004002752			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Shock	Hydroxychloroquine			S	Oral	600 Mg, Qd (Film-Coated Tablet)		Concordia	
	Hydroxychloroquine			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia	
	Cordarone			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported	
	Cordarone			S	Intravenous (not otherwise specified)	900 Mg, Qd		Not Reported	
	Noradrenaline			C		Unk		Not Reported	
	Anaklnra			C		Unk		Not Reported	
	Aspirina			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17685979	EXPEDITED (15-DAY)		HO, OT	US-ALEXION-A202005121		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19; Normocytic Anaemia; Off Label Use	Soliris 300mg			S	Intravenous (not otherwise specified)	900 Mg		Alexion	

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Soliris 300mg	S	Intravenous (not otherwise specified)	900 Mg	Alexion
Soliris 300mg	S	Intravenous (not otherwise specified)	900 Mg	Alexion
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Norepinephrine	C	Unknown	Unk	Not Reported
Ceftriaxone	C	Unknown	2 Mg, Q12h	Not Reported
Azithromycin	C	Unknown	Unk	Not Reported
Rocephin	C	Unknown	Unk	Not Reported
Propofol	C	Unknown	Unk	Not Reported
Fentanyl	C	Unknown	Unk	Not Reported
Midazolam	C	Unknown	Unk	Not Reported

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11-May-2020	17702366	EXPEDITED (15-DAY)	LT		FR-JNJFOC-20200420365		78 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Risperidone			S	Oral			Janssen
	Plaquenil			S	Oral			Not Reported
	Effexor			S	Oral			Not Reported
	Acebutolol			C	Oral			Not Reported
	Oxazepam			C	Oral			Not Reported
	Enoxaparine Sodique			C	Subcutaneous			Not Reported
	Macrogol 4000			C	Oral			Not Reported
	Amlodipine			C	Oral			Not Reported
	Clomipramine			C	Oral			Not Reported
	Zopiclone			C	Oral			Not Reported
	Nicardipine			C	Oral			Not Reported
	Hydrochlorothiazide			C	Oral			Not Reported

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11-May-2020	17711495	EXPEDITED (15-DAY)		LT, OT	FR-ASTRAZENECA-2020SE54654		18 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Cholestatic Liver Injury; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Infection; Inflammation; Pyrexia; Respiratory Disorder	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Other			Not Reported
	Hydroxychloroquine Sulfate			S	Other			Not Reported
	Loxen (Loxoprofen Sodium)			S	Intravenous (not otherwise specified)			Not Reported
	Movicol			S	Other	2 Df Bag		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5mg/ML Daily		Not Reported
	Paracetamol			C	Other			Not Reported
	Paracetamol			C	Other			Not Reported
	Doliprane			C	Unknown			Not Reported
	Doliprane			C	Unknown			Not Reported
	Lasilix			C	Other			Not Reported
	Novorapid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Diffu K			C	Other			Not Reported
	Diffu K			C	Other			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17711760	EXPEDITED (15-DAY)		OT	DE-SA-2020SA095744		45 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthralgia; Granuloma; Infective Tenosynovitis; Joint Swelling; Leukocytosis; Mycobacterium Marinum Infection; Pain In Extremity; Papule; Scab; Skin Mass; Thrombocytosis	Hydroxychloroquine	S	Oral	200 Mg, Q12h	Sanofi
	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
	Leflunomide	S	Oral	10 Mg, Qd	Sanofi
	Sulfasalazine	S	Oral	2 Df, Bid (500 Mg)	Not Reported
	Prednisolone	S	Oral	4 Mg, Qd	Not Reported
	Prednisolone	S	Oral	15 Mg, Qd	Not Reported
	Prednisolone	S	Oral	30 Mg, Qd	Not Reported
	Prednisolone	S	Oral	7.5 Mg, Qd	Not Reported
	Prednisolone	S	Oral	20 Mg, Qd (Two Weeks Before Presentation)	Not Reported
	Prednisolone	S	Oral	5 Mg, Qd	Not Reported
	Prednisolone	S	Oral	40 Mg, Qd	Not Reported
	Prednisolone	S	Oral	20 Mg, Qd	Not Reported
	Prednisolone	S	Oral	10 Mg, Qd	Not Reported
	Prednisone	S		Increased To	Not Reported
	Prednisone	S		Unk	Not Reported
	Amlodipine	C			Not Reported
	Metoprolol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17712397	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200432625		69 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance	Simponi			S	Subcutaneous			Janssen	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17712539	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010162		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Folic Acid			S	Oral	5 Mg, Qd		Not Reported	
Abdominal Pain Upper;	Hydroxychloroquine			S	Unknown	Unk		Apotex	
Alopecia; Arthralgia; Bone	Leflunomide			S	Oral	20 Mg, Qd		Apotex	
Pain; Burning Sensation;	Prednisone			S	Oral	5 Mg, Qd		Not Reported	
Choking; Condition	Actemra			S	Unknown	Unk		Not Reported	
Aggravated; Cough; Drug	Arava			S	Unknown	Unk		Not Reported	
Hypersensitivity; Drug	Calcium Folate			S	Oral	5 Mg, Qd		Not Reported	
Ineffective; Drug	Enbrel			S	Unknown	Unk		Not Reported	
Intolerance; Ear Pain;	Humira			S	Subcutaneous	Unk		Not Reported	
Facial Pain; Facial	Methotrexate			S	Unknown	25 Mg, Unk		Not Reported	
Paralysis; Fatigue;	Methotrexate			S	Oral	12.5 Mg, Q.Wk.		Not Reported	
Fibromyalgia; Foot	Orencia			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported	
Deformity; Gait	Sulfasalazine			S	Unknown	Unk		Not Reported	
Disturbance; Headache;	Xeljanz			S	Oral	5 Mg, Qd		Not Reported	
Hot Flush; Hypoaesthesia;	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
Immune System Disorder;	Acetaminophen			C	Oral	Unk		Not Reported	
Influenza Like Illness;	Acetaminophen W/Oxycodone			C	Oral	Unk		Not Reported	
Insomnia; Joint Range Of	Hydrochloride								
Motion Decreased;	Desoximetasone			C	Unknown	Unk		Not Reported	
Lipoma; Melanocytic	Ergocalciferol			C	Unknown	Unk		Not Reported	
Naevus; Musculoskeletal	Fentanyl			C	Unknown	1 Df, Unk		Not Reported	
Stiffness; Nasal	Gabapentin			C	Oral	400 Mg, Bid		Not Reported	
Discomfort;	Metformin Hydrochloride			C	Oral	Unk, Bid		Not Reported	
Nasopharyngitis; Nausea;	W/Sitagliptin								
Night Sweats; Off Label	Oxycodone Hydrochloride			C	Unknown	Unk		Not Reported	
Use; Oropharyngeal									
Discomfort; Osteoporosis;									
Pain; Pain In Extremity;									
Pain In Jaw; Pelvic									
Prolapse; Peripheral									
Coldness; Platelet Count									
Decreased; Post									
Procedural Infection;									
Rheumatoid Arthritis;									
Rhinorrhoea; Skin Mass;									
Therapeutic Product Effect									

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Decreased; Throat Irritation	Perindopril Erbumine	C	Oral	8 Mg, Qd	Not Reported
	Rabeprazole	C	Oral	180 Mg, Qd	Not Reported
	Ranitidine	C	Oral	150 Mg, Qd	Not Reported
	Rosuvastatin Calcium	C	Oral	5 Mg, Bid	Not Reported
	Sitagliptin	C	Oral	Unk, Bid	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin B 12	C	Oral	1 Df, Qd	Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd	Not Reported
	Zostavax li	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17713381	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431652			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus	Simponi			S	Subcutaneous			Janssen
	Actemra			S				Not Reported
	Azathioprine			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S				Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17718313	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000337			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia Bacterial; Pneumonia Bacterial;	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	6 G, Qd		Validus

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Staphylococcal Bacteraemia	Cefotaxime Sodium	S	Intravenous (not otherwise specified)	6 G, Qd	Validus
	Hydroxychloroquine Sulfate	S	Oral	600 Mg, Qd	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Qd	Not Reported
	Spiramycin	S	Nasal	6 Mu, Qd	Not Reported
	Vancomycin	S	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
	Vancomycin	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17718785	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200431648		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Injury; Back Pain; Discomfort; Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Intervertebral Disc Space Narrowing; Joint Stiffness; Joint Swelling; Malaise; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17728596	EXPEDITED (15-DAY)		OT	BE-ELI_LILLY_AND_COMP ANY-BE202004006858		83 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Drug Interaction; Electrocardiogram Qt Prolonged	Zyprexa Velotab 5mg	S	Oral	1/2 Tablet 2x/Day	Not Reported
	Zyprexa Velotab 5mg	S	Oral	1/2 Tablet 2x/Day	Not Reported
	Plaquenil S	S	Oral	1 Dosage Form, Bid	Not Reported
	Plaquenil S	S	Oral	1 Dosage Form, Daily	Not Reported
	Trazodone Eg	S	Oral	1/4 Tablet In Morning, At Noon, 1/2 Tablet In Evening, Patient Was Taking This Before Hospitalization	Not Reported
	Algostase Mono	C	Unknown		Not Reported
	Clexane	C			Not Reported
	Potassium 99	C	Oral	Unk, Unknown	Not Reported
	L-Thyroxine Roche	C	Unknown		Not Reported
	Perindopril	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Movicol Apelsin	C	Unknown		Not Reported
	Prolopa	C	Unknown		Not Reported
	Contramal	C	Unknown	1 Dosage Form, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17736942	EXPEDITED (15-DAY)	DS		CA-ROCHE-2589878		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Subcutaneous			Not Reported
Alopecia; Anti-Cyclic Citrullinated Peptide	Actemra			S	Subcutaneous			Not Reported
Antibody Positive;	Rituxan			S	Intravenous drip			Not Reported
Arthropathy;	Apo-Prednisone			S	Oral			Not Reported
Contraindicated Product Administered; Discomfort;	Arava			S	Oral			Not Reported
Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue;	Arava			S	Oral			Not Reported
Glossodynia; Hand Deformity; Helicobacter	Cetirizine			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported

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Infection; Hepatic Enzyme Increased;	Hydrochloride;Pseudoephedrine Hydrochloride			
Hypersensitivity; Infusion Related Reaction; Pain;	Cetirizine	S	Unknown	Not Reported
Pemphigus; Pericarditis;	Hydrochloride;Pseudoephedrine Hydrochloride			
Pregnancy; Rash;	Cimzia	S	Subcutaneous	Not Reported
Rheumatoid Arthritis;	Cimzia	S	Subcutaneous	Not Reported
Swelling; Synovitis;	Cortisone	S	Topical	Not Reported
Systemic Lupus Erythematosus; Wound	Desoximetasone	S	Oral	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Fosamax	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Salazopyrin	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17739711	EXPEDITED (15-DAY)		LT, OT	FR-ADVANS PHARMA-202004004131			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Renal Failure; Respiratory Distress	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd (Film-Coated Tablet)		Concordia

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11-May-2020	17759142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594369		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant;	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Zostavax			S	Intravenous (not			Not Reported

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Onychoclasia; Tooth Loss

Remicade	S	otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Cortisone Acetate	C	Subcutaneous	Not Reported
Desoximetasone	C		Not Reported
Diclofenac	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17759175	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698474		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Arthralgia; Back Pain;	Rituxan			S	Unknown			Not Reported
Crying; Depression; Drug	Rituxan			S				Not Reported
Ineffective; Fatigue; Joint	Arava			S	Unknown	Therapy Duration 976.0		Not Reported
Stiffness; Joint Swelling;	Enbrel			S	Subcutaneous			Not Reported
Loss Of Personal	Humira			S	Subcutaneous			Not Reported
Independence In Daily	Methotrexate Sodium			S	Unknown	Therapy Duration: 9 Years		Not Reported
Activities; Malaise;	Methotrexate Sodium			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Simponi			S	Subcutaneous			Not Reported
Pain; Pain In Extremity;								
Peripheral Swelling;								
Product Use Issue;								
Rheumatoid Arthritis;								

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Swelling; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 10 Years	Not Reported
	Sulfasalazine	S	Oral	Therapy Duration 4 Years	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 9 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764083	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2020-022169		83 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use	Olanzapine Orodispersible Tablets			S	Oral	1 Dosage Form, Once A Day,		Aurobindo
	Plaquenil			S	Oral	Day 1: 400mg 2x/D; Day 2-4:		Not Reported
	Trazodone Hydrochloride			S	Oral	1 Dosage Form, Once A Day,1/4		Not Reported
	Clexane			C	Endocervical	Unk		Not Reported
	Perindopril			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Movicol			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Levothyroxine			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Metformin			C	Unknown	2 Dosage Form, Once A		Not Reported

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Prolopa	C	Unknown	Day	Not Reported
Contramal	C	Unknown	0.5 Dosage Form, Once A Day	Not Reported
Kalium	C	Oral	1 Dosage Form, As Necessary	Not Reported
Algostase Mono	C	Unknown	Unk	Not Reported
Pradaxa	C	Unknown	3 Dosage Form, Once A Day	Not Reported
Uni Diamicron	C	Unknown	Unk	Not Reported
Magnetop	C	Oral	60 Milligram, Two Times A Day	Not Reported
			450 Milligram, Once A Day	Not Reported

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11-May-2020	17764121	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-246389		55 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported
	Rocephin			S	Oral	2 Gram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764172	EXPEDITED (15-DAY)	OT		IT-ADVANTZ PHARMA- 202004004910			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Disease Recurrence; Hypertension; Malaise; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764183	EXPEDITED (15-DAY)		HO, OT	MX-ADVANSZ PHARMA-202004004989			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia	
	Azithromycine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764488	EXPEDITED (15-DAY)		HO, OT	FR-SA-2020SA119037		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Off Label Use; Purpura; Thrombocytopenia	Plaquenil			S	Oral	Unk		Sanofi	
	Plaquenil			S				Sanofi	
	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Sanofi	
	Azithromycin			S	Oral	Unk		Not Reported	
	Esomeprazole Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Lovenox			S	Subcutaneous	Unk		Sanofi	
	Noradrenaline [Norepinephrine]			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Nimbex [Cisatracurium Besilate]			C				Not Reported	
	Loxen [Niacardipine Hydrochloride]			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Sufentanil			C				Not Reported	
	Hypnovel [Midazolam Hydrochloride]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764520	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597010		65 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Lymphoma; Off Label Use	Rituximab			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593162			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	

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Pantoprazole Magnesium	C	Unknown	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Zopiclone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764632	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595750			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594080			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Off Label Use	Anakinra	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764919	EXPEDITED (15-DAY)		OT	ES-SAKK-2020SA118587AA		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Dia		Sanofi	
	Hydroxychloroquine			S				Sanofi	
	Hydroxychloroquine			S				Sanofi	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	
	Enoxaparin Sodium			S	Subcutaneous	40 Mg Dia		Sanofi	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2gr Dia		Not Reported	
	Azithromycin			S	Oral	500 Mg Dia		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764921	EXPEDITED (15-DAY)		OT	ES-SA-2020SA117856		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi	
	Hydroxychloroquine			S				Sanofi	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S			Sanofi
Azithromycin	S	Oral	500 Mg, Qd	Not Reported
Enoxaparin Sodium	S	Subcutaneous	40 Mg	Sanofi
Roactemra	S	Intravenous (not otherwise specified)	600 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17765001	EXPEDITED (15-DAY)	DE		ES-MYLANLABS-2020M1046051		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol			S	Respiratory (inhalation)	0.1 Milligram, Q6h		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Metoclopramida /00041901/			S	Intravenous (not otherwise specified)	10 Milligram, Q8h		Mylan
	Propofol			S	Intravenous (not otherwise specified)	Unk		Mylan
	Dolquine			S	Oral	400 Milligram, Bid		Mylan
	Ipratropio Bromuro			C	Respiratory (inhalation)	20 Microgram, Q6h		Mylan
	Enoxaparina Sodica			C	Subcutaneous	Unk		Mylan
	Cefotaxima /00497602/			C	Intravenous drip	4 Milligram, Bid		Mylan
	Midazolam			C	Intravenous drip	100 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17765075	EXPEDITED (15-DAY)	DE, OT		ES-ACCORD-181155		95 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Sudden Death	Quetiapine			S	Oral			Not Reported
	Levofloxacin/Levofloxacin Mesylate			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

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Risperidone	S	Oral		Not Reported
Kaletra	S	Oral	200/50 Mg Film-Coated Tablets, 120 Tablets	Not Reported
Losartan	C	Oral		Not Reported
Clindamycin	C	Intravenous (not otherwise specified)		Not Reported
Lorazepam	C	Oral		Not Reported
Furosemide	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17765732	EXPEDITED (15-DAY)		OT	SI-PFIZER INC-2020185753		50 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder	Fragmin			S	Subcutaneous	5000 lu / 24 Hours		Pfizer	
	Hydroxychloroquine Sulphate			S	Oral	On 15apr In The Evening And On 16apr In The Morning With Dose Of 400 Mg, Then 200 Mg/12 H		Not Reported	
	Hydroxychloroquine Sulphate			S	Oral	400 Mg In The Evening		Not Reported	
	Hydroxychloroquine Sulphate			S	Oral	400 Mg In The Morning		Not Reported	
	Daleron			S	Oral	500 Mg; As Necessary, Total Dose Of 2 Tbl On 14apr And 15apr		Not Reported	
	Pantoprazol Teva			C	Oral	20 Mg; 20 Mg/Day		Not Reported	
	Folkodin Alkaloid			C	Oral	10 Mg; As Necessary 2caps/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17765761	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595576			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug	Rituximab			S	Unknown			Not Reported	

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Ineffective; Rheumatoid Arthritis	Doxycycline	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17765939	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594074			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tiaprofenic Acid	C	Unknown	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17765964	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592191		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Astigmatism; Contraindicated Product Administered; Drug Ineffective For Unapproved Indication; Dyspnoea; Hypersensitivity; Impaired Work Ability; Pain; Paraesthesia; Swelling; Therapeutic Product Effect Decreased; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Baclofen			S	Unknown			Not Reported
	Baclofen			S	Unknown			Not Reported
Sulfadiazine			S	Unknown			Not Reported	
Xeljanz			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766014	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593237			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Contraindicated Product	Actemra	S	Unknown	Not Reported
Administered; Drug	Enbrel	S	Unknown	Not Reported
Ineffective; Rheumatoid Arthritis; Rheumatoid	Humira	S	Subcutaneous	Not Reported
Factor Positive; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766223	EXPEDITED (15-DAY)		DS	CA-ROCHE-2596648		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766384	EXPEDITED (15-DAY)		OT	FR-ACCORD-181003		81 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin Sandoz			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766429	DIRECT	Y	OT			55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Hypoglycaemia	Hydroxychloroquine			S	Oral			Not Reported	
	Glimeperide			C				Not Reported	
	Cyclosporine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766484	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020185527		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperkalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer	
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Telmisartan			S	Oral	40 Mg, 1x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766486	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020185579		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer	
	Azithromycin			S				Pfizer	
	Metamizole			S	Intravenous (not otherwise specified)	2 G, 4x/Day (2 G Every 6 Hours)		Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (400 Mg/Day)		Not Reported	
	Paracetamol			S	Intravenous (not otherwise specified)	1 G, 3x/Day (1g Every 8 Hours)		Not Reported	

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Detailed Report

Tocilizumab S Intravenous (not otherwise specified) 600 Mg, Single Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766918	EXPEDITED (15-DAY)		HO	CA-SA-2020SA118445		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder	Plaquenil			S		Unk		Sanofi
	Arava			S				Sanofi
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cortisone			S		10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766966	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-15268			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment; Synovitis	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Otezla			S	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17767571	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2020M1046274		29 YR	Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Toxic	Hydroxychloroquine			S	Unknown	100 Milligram Bid, Had		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Epidermal Necrolysis

Prednisolone	C	Unknown	30 Milligram, Qd	Mylan
Prednisolone	C	Unknown	60 Milligram, Qd	Mylan
Mycophenolate Mofetil	C	Unknown	1.5 Gram, 0.5 Day	Mylan

Been Receiving For 2 Months

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17767604	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020185539		55 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Abnormal; Nausea; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	750 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Rocephin			C	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17767609	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2020M1045896			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Intentional Product Misuse; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17767962	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-013311		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days		Bausch And Lomb
	Dexametasona			S				Bausch And Lomb
	Hidroxyclozoquina			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hidroxiclороquina	S						Not Reported
	Enoxaparina	S	Subcutaneous					Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Total				Not Reported
	Tocilizumab	S						Not Reported
	Azitromicina	S	Intravenous (not otherwise specified)					Not Reported
	Azitromicina	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17768202	EXPEDITED (15-DAY)		OT	US-EMERGENT BIOSOLUTIONS-20000341SP			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Rheumatoid Arthritis	Narcan			S	Unknown	4 Milligram		Emergent Biosolutions	
	Prednisone			S	Unknown			Not Reported	
	Wellbutrin			S	Unknown	300 Milligram, Qd		Not Reported	
	Wellbutrin			S	Unknown	150 Milligram, Qd		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Cyclobenzaprine Hcl			S	Unknown	Unk		Not Reported	
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17768204	EXPEDITED (15-DAY)		OT	US-EMERGENT BIOSOLUTIONS CANADA INC.-20000340SP		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis	Narcan			S	Unknown	4 Milligram		Emergent Biosolutions	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Wellbutrin			S	Unknown	150 Milligram, Qd		Not Reported	
	Wellbutrin			S	Unknown	300 Milligram, Qd		Not Reported	
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	S	Oral	10 Milligram Daily; 60/Btl	Not Reported
Cyclobenzaprine Hcl	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	9459293	EXPEDITED (15-DAY)		OT	CA-ROCHE-1162770		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Diastolic Increased; Blood Pressure Fluctuation;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Blood Pressure Increased; Blood Pressure Systolic Abnormal; Blood Pressure Systolic Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Cataract; Cystitis; Drug Intolerance; Dry Mouth; Dyslipidaemia; Fall;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Hepatic Enzyme Increased; Inflammation; Joint Swelling;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Musculoskeletal Stiffness; Nasopharyngitis; Osteoporosis; Painful Respiration; Pharyngeal Mass; Pneumonia; Poor Venous Access; Synovitis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Upper Limb Fracture; Weight Increased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Synthroid			C				Not Reported
	Flexeril [Cyclobenzaprine Hydrochloride]			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Tylenol			C				Not Reported
	Folic Acid			C				Not Reported
	Garlic [Allium Sativum]			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	C	Unknown	Not Reported
Sulfasalazine	C	Oral	Not Reported
Naprosyn [Naproxen]	C		Not Reported
Calcium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	10296970	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1105839		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthritis; Blood Creatinine Decreased; Condition Aggravated; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count Decreased; Ocular Procedural Complication; Optic Neuritis; Pain; Photophobia; Post Procedural Complication; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Tinnitus; Vision Blurred; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)	First Rpap Dose		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown Dosing Details		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Folic Acid			S	Unknown	Once Daily Except Friday		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Discontinued Due To Ophthalmic Problems		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Acetaminophen			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Fosavance	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Diphenhydramine Hcl	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Hydrocortisone	C	Intravenous (not otherwise specified)	Not Reported
	Humira	C		Not Reported
	Orencia	C		Not Reported
	Remicade	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	12248361	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1737509		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Diabetes Mellitus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Inadequate Control; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Spinal Operation; Sputum Discoloured; Thrombosis	Actemra			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Warfarin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Warfarin	S	Unknown	Not Reported
	Amitriptyline	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	12309292	EXPEDITED (15-DAY)	HO		CA-ROCHE-1746971			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 6 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 581 Days		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 581 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	13059040	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015749		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Hepatotoxicity; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Apo-Leflunomide			S	Oral	10 Unk, Unk		Apotex
	Apo-Prednisone			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Leflunomide			S	Oral	10 Mg, Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S	Unknown	300 Mg, Unk		Apotex
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazin			S	Unknown	2 G, Unk		Not Reported
	Sulfasalazin			S	Unknown	2 Mg, Unk		Not Reported
	Sulfasalazin			S	Unknown	500 Mg, Unk		Not Reported
	Arava			S	Unknown	10 Mg, Unk		Not Reported
	Arava			S	Unknown	20 Mg, Unk		Not Reported
	Celebrex			S	Unknown	50 Mg, Q.Wk.		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg, Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
Methotrexate			S	Subcutaneous	2.5 Mg, Unk		Not Reported	
Methotrexate			S	Subcutaneous	10 Mg, Unk		Not Reported	
Orencia			S	Subcutaneous	250 Mg, Unk		Not Reported	
Plaquenil /00072602/			S	Unknown	300 Mg, Unk		Not Reported	

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Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Unknown	2 G, Unk	Not Reported
Sulfasalazine	S	Unknown	2 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	13067408	EXPEDITED (15-DAY)	DS		CA-ROCHE-1871510		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Alopecia; Anti-Cyclic								
Citrullinated Peptide	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported
Antibody Positive;								
Arthralgia; Arthropathy;	Arava			S	Oral			Not Reported
Condition Aggravated;	Arava			S	Oral			Not Reported
Contraindicated Product	Arava			S	Unknown			Not Reported
Administered; Discomfort;	Cimzia			S	Subcutaneous			Not Reported
Drug Ineffective; Drug	Cimzia			S	Unknown			Not Reported
Intolerance; Duodenal	Cimzia			S	Unknown			Not Reported
Ulcer Perforation;	Cimzia			S	Unknown			Not Reported
Exposure During	Desoximetasone			S	Oral			Not Reported
Pregnancy; Fatigue;	Desoximetasone			S	Unknown			Not Reported
Glossodynia; Hand	Desoximetasone			S	Oral			Not Reported
Deformity; Helicobacter	Desoximetasone			S	Unknown			Not Reported
Infection; Hepatic Enzyme	Desoximetasone			S	Oral			Not Reported
Increased; Hip	Enbrel			S	Subcutaneous			Not Reported
Arthroplasty;	Enbrel			S	Subcutaneous			Not Reported
Hypersensitivity; Infusion	Fosamax			S	Oral			Not Reported
Related Reaction; Injury;	Fosamax			S	Unknown			Not Reported
Joint Swelling; Knee	Fosamax			S	Unknown			Not Reported
Arthroplasty; Live Birth;	Humira			S	Subcutaneous			Not Reported
Maternal Exposure During	Humira			S	Subcutaneous			Not Reported
Pregnancy;	Humira			S	Subcutaneous			Not Reported
Musculoskeletal Stiffness;								
Pain; Pemphigus;								
Pericarditis; Pregnancy;								
Product Use Issue; Rash;								
Rheumatoid Arthritis;								
Rheumatoid Factor								

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Positive; Swelling;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Synovitis; Systemic Lupus	Hydroxychloroquine Sulfate	S			Not Reported
Erythematosis;	Orencia	S	Subcutaneous	Therapy Duration: 11 Months	Not Reported
Therapeutic Product Effect					
Decreased; Treatment	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11 Months	Not Reported
Failure; Wound					
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Subcutaneous		Not Reported
Methotrexate	S	Oral	Therapy Duration: 11 Years	Not Reported
Methotrexate	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S			Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Cetirizine	S	Unknown		Not Reported
Cetirizine	S			Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Cortisone Acetate	S	Topical		Not Reported
Cortisone Acetate	S	Oral		Not Reported
Cortisone Acetate	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Cutaneous		Not Reported
Topicort [Desoximetasone]	S	Oral		Not Reported
Topicort [Desoximetasone]	S	Other		Not Reported
Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
Topicort [Desoximetasone]	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Apo Hydroxyquine	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown		Not Reported
Cortisone	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported
Diclofenac	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paracetamol	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	13224700	EXPEDITED (15-DAY)		OT	CA-ROCHE-1890670			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	10/--/1997 To 02/--/1999, Duration- 2 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Sodium Aurothiomalate			C				Not Reported
	Arava			C	Unknown			Not Reported
	Leflunomide			C	Unknown	Duration- 11 Years		Not Reported
	Actemra			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	13625046	EXPEDITED (15-DAY)		OT	CA-HORIZON-VIM-0072-2017		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Vimovo			S	Oral	Unknown Dose		Not Reported
Antinuclear Antibody Positive; Arthralgia;	Methotrexate			S	Oral	20 Mg Weekly, Restarted 2008		Not Reported
Atelectasis; Bursitis; Conjunctivitis;	Naproxen			S	Oral	500 Mg Bid, 250 Mg Bid, 1000 Mg Bid		Not Reported
Contraindicated Product Administered;	Enbrel			S	Subcutaneous	50 Mg Once Weekly		Not Reported
Crepitations; Cushingoid;	Pantoloc			S	Oral	Daily		Not Reported
Drug Ineffective; Dry Eye; Dry Mouth; Dyspnoea;	Alendronic Acid			S	Oral			Not Reported
Erythema; Eye Irritation; Eye Pain; Feeling Jittery;	Amitriptyline Hydrochloride			S	Oral	75 Mg Daily		Not Reported
Fibromyalgia; Flank Pain; Haemoglobin Decreased;	Depo Medrol			S	Intra-articular			Not Reported
Impaired Work Ability; Infection; Interstitial Lung Disease; Joint Effusion;	Humira			S	Subcutaneous	40 Mg Unknown, Solution For Injection		Not Reported
Joint Swelling; Lung Disorder; Malaise;	Imuran			S		150 Mg		Not Reported
Musculoskeletal Pain;	Lyrica			S	Oral	300 Mg Qd, 150 Mg Bid		Not Reported
Musculoskeletal Stiffness;	Meloxicam			S		150 Mg Daily		Not Reported
Nausea; Neoplasm	Prednisone			S		15 Mg Qd		Not Reported
Malignant; Nodule; Ocular Hyperaemia; Pain; Pain In Extremity; Peripheral Swelling; Photophobia;	Ranitidine			S	Oral	300 Mg Qd		Not Reported
Pleuritic Pain; Pneumonia; Pruritus; Rash; Red Blood Cell Count Decreased;	Ratio-Oxycocet			S				Not Reported
Rheumatoid Arthritis;	Septra			S				Not Reported
Rheumatoid Nodule;	Sulfasalazine			S	Oral	1 G, Daily		Not Reported
Scleritis; Swelling Face; Synovial Cyst; Synovial Fluid Analysis;	Tofacitinib			S	Oral	5 Mg Bid And 10 Mg Daily		Not Reported
Tenderness;	Folic Acid			C				Not Reported
Tenosynovitis Stenosans;	Plaquenil			C				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Amitriptyline			S	Oral	75 Mg Qd		Not Reported
	Apo-Meloxicam			S				Not Reported
	Apo-Naproxen			S	Oral	500 Mg Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapeutic Product Effect Decreased; Thrombosis; Ulcer; Visual Impairment; Wheezing	Apo-Prednisone	S		15 Mg Daily	Not Reported
	Apo-Ranitidine	S	Oral	150 Mg Bid	Not Reported
	Teva-Oxycocet	S			Not Reported
	Apo-Alendronate	S			Not Reported
	Bactrim	S			Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	S			Not Reported
	Esomeprazole Magnesium	S	Oral		Not Reported
	Ranitidine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tofacitinib	S	Oral	5 Mg Two Times Daily	Not Reported
	Celebrex	C			Not Reported
	Celebrex	C			Not Reported
	Eltroxin	C			Not Reported
	Dexilant	C			Not Reported
	Codeine	C		Qd	Not Reported
	Cimzia	C			Not Reported
	Cannabis Sativa	C			Not Reported
	Orencia	C	Unknown		Not Reported
	Pantoprazole	S			Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Amoxicillin	S	Unknown		Not Reported
	Mobicox	S			Not Reported
	Pregabalin	S	Oral		Not Reported
	Azathioprine	S			Not Reported
	Hydroxychloroquine Phosphate	S			Not Reported
	Elavil	S			Not Reported
	Adalimumab	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	13975158	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2017AP018001			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Iron Abnormal; Disease Progression;	Hydroxychloroquine			S	Unknown	Unk		Apotex	
	Cyclosporine			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Actemra	S	Unknown	640 Mg, Q.Wk.	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	200 Mg, Q.Wk.	Not Reported
	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	400 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Q.Wk.	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	13995479	EXPEDITED (15-DAY)		OT	CA-ROCHE-1995131		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	S	Oral	Not Reported
Dorzolamide	C		Not Reported
Hydrochloride/Timolol Maleate			
Estradiol	C		Not Reported
Furosemide	C		Not Reported
Valsartan	C		Not Reported
Xalatan	C	Ophthalmic	Not Reported
Baclofen	C		Not Reported
Levaquin	C		Not Reported
Baclofen	C		Not Reported
Furosemide	C		Not Reported
Gravol Ginger	C		Not Reported
Potassium Chloride	C		Not Reported
Valsartan	C		Not Reported
Zingiber Officinale	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	14161744	EXPEDITED (15-DAY)		OT	CA-ROCHE-2014675			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rituximab			S	Unknown			Not Reported
Acne Cystic; Condition	Anakinra			S	Unknown			Not Reported
Aggravated;	Arava			S	Oral			Not Reported
Contraindicated Product	Enbrel			S	Unknown			Not Reported
Administered; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Insomnia	Humira			S	Subcutaneous	Prefilled Syringe; Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vioxx	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	14166039	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210592			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg,Qd		Sanofi
	Methotrexate			S	Oral	175 Mg,Qw		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg,Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk Unk,Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	14739695	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104045		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Contraindicated Product Administered; Drug Ineffective;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

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Laboratory Test Abnormal; Red Blood Cell Sedimentation Rate Abnormal	Celebrex	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	14746352	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP009049			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Cyclosporine			S	Unknown	Unk		Apotex
Arthralgia; Blood	Hydroxychloroquine			S	Unknown	Unk		Apotex
Creatinine Increased;	Actemra			S	Unknown	Unk		Not Reported
Contraindicated Product	Enbrel			S	Unknown	Unk		Not Reported
Administered; Drug	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
Hypersensitivity; Drug	Methotrexate			S	Unknown	Unk		Not Reported
Ineffective; Drug	Orencia			S	Unknown	125 Mg, Q.Wk.		Not Reported
Intolerance; Loss Of	Rituxan			S	Unknown	Unk		Not Reported
Personal Independence In	Sulfasalazine			S	Unknown	Unk		Not Reported
Daily Activities; Mobility	Tofacitinib			S	Unknown	Unk		Not Reported
Decreased;	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
Musculoskeletal Pain;	Gabapentin			C	Unknown	Unk		Not Reported
Neck Pain; Pain In								
Extremity; Pain In Jaw;								
Rheumatoid Arthritis								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tylenol Arthritis Pain	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	15343031	EXPEDITED (15-DAY)		OT	CA-ROCHE-2178204		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituximab			S	Intravenous drip	Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Venlafaxine Hydrochloride			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Hydrodiuril			C	Unknown			Not Reported
	M-Eslon			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Venlafaxine Hydrochloride			C	Oral			Not Reported
	Statex [Morphine Sulfate]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	15415874	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187974			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Contraindicated Product	Actemra	S	Unknown	Not Reported
Administered; Drug	Arava	S	Oral	Not Reported
Ineffective; Drug	Cimzia	S	Subcutaneous	Not Reported
Intolerance; Pain;	Enbrel	S	Unknown	Not Reported
Rheumatoid Arthritis;	Humira	S	Subcutaneous	Not Reported
Therapeutic Product Effect	Methotrexate	S	Oral	Not Reported
Incomplete; Therapeutic	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Product Effect Incomplete;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Treatment Failure	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported
	Tofacitinib Citrate	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	15562825	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015053449		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product	Enbrel			S		Unk		Unknown	
Administered; Contusion;	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer	
Drug Ineffective; Drug	Methotrexate Sodium			S	Oral	22.5 Mg, Weekly		Pfizer	
Intolerance; Fatigue;	Methotrexate Sodium			S	Oral	25 Mg, Qd		Pfizer	
Treatment Failure									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Oral	25 Mg, Weekly	Pfizer
Methotrexate Sodium	S	Unknown	22.5 Mg, Qwk	Pfizer
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Actemra	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S		10 Mg, Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Hydroxyquine	S	Oral	10 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	15875870	EXPEDITED (15-DAY)		OT	PHHY2019DE016444		60 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Cell Carcinoma; Restlessness	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Methotrexate			S	Unknown	17.5 Mg, Unk		Novartis
	Methotrexate			S	Unknown	15 Mg, Unk		Novartis
	Benepali			S	Unknown	50 Mg, Qw		Not Reported
	Benepali			S	Unknown	50 Mg		Not Reported
	Hcq			S	Unknown	200 Mg, Unk		Not Reported
	Hcq			S	Unknown	300 Mg, Qd		Not Reported
	Tocilizumab			S	Unknown	162 Mg		Not Reported
	Chloroquine			C	Unknown	300 Mg, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg		Not Reported
	Orencia			C	Unknown	125 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	15949612	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US-			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2019VAL000034

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Clopidogrel Bisulfate			S	Unknown	Unk		Not Reported
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Loperamide			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Potassium			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk		Not Reported
	Trazodone Hydrochloride			S	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qod		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Humira			S				Not Reported
	Flomax /00889901/			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16043043	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057806			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S		20 Mg, Unk		Sanofi
	Hydroxychloroquine			S		400 Mg, Unk		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Actemra			S		8 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Enbrel			S		Unk Unk, Unk		Not Reported
	Orencia			S		750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sulfasalazine			C		Unk Unk, Unk		Not Reported
	Meloxicam			C	Unknown	Unk Unk, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16046577	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057860			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S		20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Sulfasalazine			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16046593	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057717			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspepsia; Joint Swelling; Therapy Partial Responder	Arava			S	Unknown	Unk Unk, Unk		Sanofi	
	Leflunomide			S	Unknown	20 Mg		Sanofi	
	Hydroxychloroquine			S	Unknown	Unk Unk, Unk		Sanofi	
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported	
	Sulfasalazine			S	Unknown	Unk, Unk		Not Reported	
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16046595	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057730		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Lower Respiratory Tract Infection; Nasal Congestion; Rhinorrhoea; Synovitis	Arava			S	Unknown	Unk Unk, Unk		Sanofi	
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi	
	Enbrel			S	Unknown	Unk Unk, Unk		Not Reported	
	Cimzia			S	Unknown	Unk Unk, Unk		Not Reported	
	Salazopyrin			C	Unknown	Unk Unk, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16046597	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057910			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint	Leflunomide			S	Unknown	20 Mg		Sanofi	
	Plaquenil			S	Unknown	200 Mg, Bid		Sanofi	

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Swelling; Pain; Therapeutic Product Effect Decreased	Methotrexate	S	Unknown	20 Mg	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Unknown	(4-6 Months Duration)	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16047223	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058618		33 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Plaquenil			S	Unknown	200 Mg, Qow		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	20 Mg, Qw		Not Reported
	Actemra			S	Unknown	5 Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qw		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qw		Not Reported
	Methotrexate Sodium			S		20 Mg, Qw		Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16048334	EXPEDITED (15-DAY)		OT	CA-SA-2019SA059173			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Enbrel	S	Unknown	50 Mg, Qw	Not Reported
	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
	Sulfasalazine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16051263	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057562			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Arava			S	Oral	20 Mg, Unk		Sanofi
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi
	Sulfasalazine			S	Unknown	1000 G, Unk		Not Reported
	Prednisone			S	Oral	5 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Unknown	20 Mg, Unk		Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16075449	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012871		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Unknown	70 Milligram, Once A Day		Aurobindo
	Alendronic Acid Tablets			S	Oral	70 Milligram, Every Week		Aurobindo
	Actemra			S	Unknown	360 Milligram		Not Reported
	Actemra			S	Unknown	680 Milligram, Every		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eruption; Drug				Month	
Hypersensitivity; Drug	Actemra	S	Unknown	Unk	Not Reported
Ineffective; Granuloma	Apo-Leflunomide	S	Oral	Unk	Not Reported
Skin; Hypercalcaemia;	Apo-Leflunomide	S	Unknown	Unk	Not Reported
Inflammation; Infusion	Codeine	S	Unknown	Unk	Not Reported
Related Reaction; Loss Of	Enbrel	S	Unknown	25 Milligram, 2 Every 1	Not Reported
Personal Independence In				Week	
Daily Activities;	Enbrel	S	Unknown	50 Milligram, Every Week	Not Reported
Panniculitis; Peripheral	Humira	S	Subcutaneous	40 Milligram, Every 2	Not Reported
Swelling; Rash; Rash				Week	
Pruritic; Rheumatoid	Humira	S	Subcutaneous	40 Milligram, 11 Every 2	Not Reported
Arthritis; Rheumatoid				Weeks	
Nodule; Skin Necrosis;					
Skin Ulcer; Therapeutic					
Response Decreased;					
Ulcer					
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Every	Not Reported
				Week	
	Methotrexate	S	Unknown	12.5 Milligram, Every	Not Reported
				Week	
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	12 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Every Week	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Every Week	Not Reported
	Methotrexate	S	Oral	10 Milligram, Every Week	Not Reported
	Myochrysine	S	Unknown	Unk	Not Reported
	Orencia	S	Unknown	780 Milligram, Every Week	Not Reported
	Orencia	S	Unknown	780 Milligram	Not Reported
	Remicade	S	Intravenous (not	Unk	Not Reported
			otherwise specified)		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	Unknown	1000 Milligram, Two Times A Day	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, Two Times A Day	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, Every Month	Not Reported
Alendronate Sodium	C	Unknown	70 Milligram, Every Week	Not Reported
Ciclosporin	C	Unknown	150 Milligram, Once A Day	Not Reported
Prednisone	C	Unknown	10 Milligram, Once A Day	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16462890	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-1910		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fall; Gastrointestinal Disorder; Interstitial Lung Disease; Liver Function Test Increased; Sepsis; Therapeutic Product Effect Decreased; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Pamidronate Disodium			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Cyclosporin			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxycycline Hyclate	S	Unknown	Not Reported
6-Mercaptopurine Monohydrate	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
Tenoxicam	S	Unknown	Not Reported
Bromocriptine	S	Unknown	Not Reported
Ustekinumab	S	Unknown	Not Reported
Colchicine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Ciclosporin	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Mercaptopurine	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Tenoxicam	C	Unknown	Not Reported
Ustekinumab	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16537906	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA177580		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Hydroxychloroquine			S	Oral	400 Mg, Bid		Sanofi
Diverticulitis; Drug	Methotrexate			S	Subcutaneous	0.8 MI, Qw		Not Reported
Hypersensitivity; Drug	Leflunomide			S	Unknown	Unk, Unk		Sanofi
Ineffective; Drug	Prednisone			S	Unknown	Unk, Unk		Not Reported
Intolerance; Dyspnoea;	Celecoxib			S	Oral	200 Mg, Bid		Not Reported
Hernia; Joint Destruction;								
Nausea; Rheumatoid								
Arthritis; Stoma								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Complication	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Actemra	S	Unknown	Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16753500	EXPEDITED (15-DAY)		OT	CA-ROCHE-2384248		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Larynx Irritation; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous	Therapy Duration-1.0 Day(S)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16811263	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC- 20190905771			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal	Paracetamol			S	Unknown			Johnson And Johnson
	Paracetamol			S	Unknown			Johnson And Johnson
	Tylenol Arthritis Pain 8h			S	Unknown			Johnson And Johnson
	Paracetamol/Diphenhydramine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported

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Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Doxycycline	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown	Hydroxychloroquine /00072603/	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Leflunomide	S	Oral		Not Reported
	Orencia	S	Unknown		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Plaquenil /00072602/	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Paracetamol/Codeine Phosphate	C	Unknown		Not Reported
	Oros Hydromorphone Hcl	C	Unknown		Not Reported
	Tylenol W/ Codeine No. 3	C	Unknown		Not Reported
	Celebrex	C	Oral		Not Reported
	Celecoxib	C	Unknown		Not Reported
	Meloxicam	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Methotrexate	C	Unknown		Not Reported
	Synthroid	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported
	Codeine	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16825327	EXPEDITED (15-DAY)		OT	CA-ROCHE-2404671			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituxan			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16878285	EXPEDITED (15-DAY)		OT	CA-ROCHE-2107873		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	
Sulfasalazine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Naproxen	C	Unknown	Not Reported
Atorvastatin Calcium	C		Not Reported
Bisoprolol	C		Not Reported
Digoxin	C		Not Reported
Folic Acid	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Naproxen	C		Not Reported
Nifedipine	C		Not Reported
Synthroid	C		Not Reported
Toloxin [Digoxin]	C		Not Reported
Valsartan	C		Not Reported
Xarelto	C		Not Reported
Zinc Citrate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	16913173	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2428710		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Entesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia;	Rituxan			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported

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Inflammation; Infusion	Enbrel	S	Unknown	Not Reported
Related Reaction; Loss Of	Enbrel	S		Not Reported
Personal Independence In	Enbrel	S		Not Reported
Daily Activities; Nausea;	Humira	S	Subcutaneous	Not Reported
Panniculitis; Peripheral	Humira	S	Subcutaneous	Not Reported
Swelling; Psoriatic	Hydroxychloroquine	S	Unknown	Not Reported
Arthropathy; Rash; Rash	Hydroxychloroquine	S	Unknown	Not Reported
Pruritic; Red Blood Cell	Hydroxychloroquine	S	Unknown	Not Reported
Sedimentation Rate	Hydroxychloroquine	S	Unknown	Not Reported
Increased; Rheumatoid	Hydroxychloroquine	S	Unknown	Not Reported
Arthritis; Rheumatoid	Hydroxychloroquine	S	Unknown	Not Reported
Nodule; Skin Necrosis;	Methotrexate	S	Subcutaneous	Not Reported
Skin Ulcer; Synovitis;	Methotrexate	S	Subcutaneous	Not Reported
Tendonitis; Tenosynovitis;	Methotrexate	S	Subcutaneous	Not Reported
Tongue Disorder; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apo-Ibuprofen	S	Oral	Not Reported
	Apo-Hydroxyquine	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported

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Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Infliximab	S	Oral	Not Reported
Ibuprofen	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Motrin [Ibuprofen]	S	Oral	Not Reported
Otezla	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Not Reported
Alendronate	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C		Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Colchicine	C	Oral	Not Reported
Dexilant	C	Unknown	Not Reported
Febuxostat	C		Not Reported
Folic Acid	C		Not Reported
Gravol	C		Not Reported
Mogadon	C	Oral	Not Reported
Nitrazepam	C	Oral	Not Reported
Oxycodone	C		Not Reported
Uloric	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17233158	EXPEDITED (15-DAY)		HO	CA-ROCHE-2511749			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Desoximetasone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17286449	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521764			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Abatacept	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17324328	EXPEDITED (15-DAY)		OT	MQ-ALKEM LABORATORIES LIMITED-MQ-ALKEM- 2020-00067		53 YR	Female	MTQ

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acarodermatitis; Hyperkeratosis	Mycophenolate Mofetil			S	Unknown	Unk		Alkem
	Azathioprine			S	Unknown	Unk		Alkem
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Belimumab			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17417741	EXPEDITED (15-DAY)		HO	CA-ROCHE-2547886		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Hip	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthroplasty; Infection;	Leflunomide	S	Unknown	Not Reported
Knee Arthroplasty;	Methotrexate	S	Unknown	Not Reported
Rheumatoid Arthritis;	Orencia	S	Unknown	Not Reported
Seronegative Arthritis;	Simponi	S	Unknown	Not Reported
Spinal Fusion Surgery;	Simponi	S	Unknown	Not Reported
Therapeutic Product Effect	Simponi	S	Unknown	Not Reported
Decreased; Type 2	Sulfasalazine	S	Unknown	Not Reported
Diabetes Mellitus; Wound	Hydroxychloroquine	S	Unknown	Not Reported
Infection	Apo-Leflunomide	S	Unknown	Not Reported
	Naprosyn [Naproxen]	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17438985	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552195			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Decreased;	Rituxan			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Drug	Methotrexate			S	Unknown			Not Reported
Ineffective; Fibromyalgia;	Arava			S	Unknown			Not Reported
Nasal Congestion;	Enbrel			S	Unknown			Not Reported
Nasopharyngitis; Serum	Humira			S	Subcutaneous			Not Reported
Ferritin Decreased; Viral	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Upper Respiratory Tract	Orencia			S	Unknown			Not Reported
Infection	Remicade			S	Intravenous (not			Not Reported
					otherwise specified)			
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			C	Unknown			Not Reported
	Sulfate]							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17477176	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2557988			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Joint Arthroplasty; Rheumatoid Arthritis; Weight Increased; Wheelchair User	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17506284	EXPEDITED (15-DAY)		OT	CA-ROCHE-2560155		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Minocycline	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Amoxicillin;Clavulanate Potassium	C		Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Adalimumab	C		Not Reported
Amoxicillin	C		Not Reported
Amoxicillin Trihydrate	C		Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C		Not Reported
Bcg Vaccine	C	Unknown	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Hydroxychloroquine	C	Subcutaneous	Not Reported

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Hydroxychloroquine	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Risedronate	C	Oral	Not Reported
Gold	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17531084	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2563674		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17681180	EXPEDITED (15-DAY)		DS, HO, LT, OT	NVSC2020SK101566			Female	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Growth Restriction;	Metoprolol Tartrate			S	Transplacental	Unk		Novartis
	Etamsylate			S	Transplacental	Unk		Not Reported

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Oligohydramnios; Premature Baby	Dexamethasone	S	Transplacental	Unk	Not Reported
	Potassium Chloride	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Prednisone	S	Transplacental	Unk	Not Reported
	Acetaminophen (Paracetamol)	S	Transplacental	Unk	Not Reported
	Calcium Carbonate	S	Transplacental	Unk	Not Reported
	Folic Acid	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Methylprednisolone	S	Transplacental	Unk	Not Reported
	Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Omeprazole	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	Unk	Not Reported
	Penicillin G Benzathine	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Cefotaxime	S	Transplacental	Unk	Not Reported
	Hydrocortisone	S	Transplacental	Unk	Not Reported
	Vitamin K Nos	S	Transplacental	Unk	Not Reported
	Magnesium Lactate	S	Transplacental	Unk	Not Reported
	Bisulepin	S	Transplacental	Unk	Not Reported
	Nadroparine	S	Transplacental	Unk	Not Reported
	Privigen	S	Transplacental	Unk	Not Reported
	Flebogamma Dif	S	Transplacental	Unk	Not Reported
	Vitamin B Complex	S	Transplacental	Unk	Not Reported
	Albumin	S	Transplacental	Unk	Not Reported
	Ornidazole	S	Transplacental	Unk	Not Reported
	Cefixime	S	Transplacental	Unk	Not Reported
	Vulmizolin	S	Transplacental	Unk	Not Reported
	Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D S Transplacental Unk Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17687062	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP013397		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
Adverse Drug Reaction;	Hydroxychloroquine			S	Unknown	Unk		Apotex
Alopecia; Anti-Cyclic	Hydroxychloroquine			S	Oral	Unk		Apotex
Citrullinated Peptide	Prednisone			S	Intravenous (not otherwise specified)	Unk		Not Reported
Antibody Positive;								
Arthropathy; Condition								
Aggravated;								
Contraindicated Product	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
Administered; Discomfort;	Folic Acid			S	Unknown	0.5 Mg, Unk		Not Reported
Drug Ineffective; Drug	Folic Acid			S	Oral	25 Mg, Unk		Not Reported
Intolerance; Fatigue;	Folic Acid			S	Unknown	1 Mg, Unk		Not Reported
Glossodynia; Hand	Apo-Prednisone			S	Unknown	Unk		Apotex
Deformity; Hepatic	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
Enzyme Increased; Hip	Cetirizine			S	Unknown	Unk		Apotex
Arthroplasty;	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
Hypersensitivity; Infusion	Diclofenac			S	Unknown	Unk		Apotex
Related Reaction;	Leflunomide			S	Oral	Unk		Apotex
Intentional Product Use	Acetaminophen			S	Unknown	Unk		Apotex
Issue; Joint Swelling;	Apo Folic Acid			S	Unknown	Unk		Not Reported
Knee Arthroplasty;	Winpred			S	Oral	Unk		Apotex
Maternal Exposure During	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
Pregnancy; Off Label Use;	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
Pain; Pemphigus;	Sulfasalazine			S	Oral	1 G, Unk		Not Reported
Pericarditis; Rash;	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
Rheumatoid Arthritis;	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
Rheumatoid Factor	Actemra			S	Unknown	Unk		Not Reported
Positive; Swelling;								
Synovitis; Systemic Lupus								
Erythematous; Treatment								
Failure; Wound								

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Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S	Oral	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Cimzia	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Fosamax	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40mg/0.8ml	Not Reported
Humira	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Unk	Not Reported
Methotrexate	S	Unknown	20 Mg, Qd	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Desoximetasone	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown	Unk	Not Reported

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Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Topicort Lp	S	Unknown	Unk	Not Reported
Topicorte	S	Subcutaneous	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17705423	EXPEDITED (15-DAY)		DE, LT, OT	FR-ADVANSZ PHARMA-202004003544			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Multiple Organ Dysfunction Syndrome; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Metoclopramide Hydrochloride			C		Unk		Not Reported
	Ciprofloxacin			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Piperacilline/Tazobactam			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported

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Lidocaine	C	Unk	Not Reported
Enoxaparin Sodium	C	Unk	Not Reported
Methylprednisolone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17716028	EXPEDITED (15-DAY)		DE, OT	FR-ADVANSZ PHARMA-202004004070			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Off Label Use; Renal Failure; Respiratory Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia	
	Ceftriaxone			C		Unk		Not Reported	
	Methylprednisolone			C		Unk		Not Reported	
	Oxazepam			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17718033	EXPEDITED (15-DAY)		HO, LT, OT	IT-ACCORD-179592		36 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Creatinine Increased; Coronavirus Infection; Diarrhoea; Drug Interaction; Drug Level Above Therapeutic; Glomerular Filtration Rate Abnormal; Nausea; Pneumonia; Vomiting	Tacrolimus			S		Bid, 3 Mg Bid		Accord	
	Ceftriaxone			S				Not Reported	
	Lopinavir/Ritonavir			S		400mg/100mg Bid		Not Reported	
	Hydroxychloroquine			S		Bid		Not Reported	
	Methylprednisolone			S		6.5 Mg Daily		Not Reported	
	Allopurinol			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Ramipril			C				Not Reported	
	Omeprazole			C				Not Reported	
	Tacrolimus			S		Bid, 3 Mg Bid		Accord	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17719494	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1227982		50 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiomyopathy; Cardiotoxicity	Hydroxychloroquine			S	Unknown			Teva
	Rituximab			C	Unknown			Not Reported
	Cyclophosphamide			C	Unknown			Not Reported
	Doxorubicin Hydrochloride			C	Unknown			Not Reported
	Vincristine			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17720141	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC- 2020167361		75 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Lopinavir + Ritonavir			S	Oral	2 Df, 2x/Day		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Prednisone			C	Oral	20 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17726348	EXPEDITED (15-DAY)		OT	FR-ADVANS PHARMA- 202004004068			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Pneumonia; Renal Failure	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Hydroxychloroquine			S				Concordia
	Cefepime			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17737424	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-021232		96 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin Film-Coated Tablets			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported
	Lasix			C	Unknown	25 Milligram, Once A Day		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Normix			C	Unknown	Unk		Not Reported
	Dobetin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Deltacortene			C	Unknown	Unk		Not Reported
	Pantorc			C	Unknown	20 Milligram, Once A Day		Not Reported
	Cardirene			C	Unknown	75 Milligram, Once A Day		Not Reported
	Metoprololo			C	Unknown	50 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17747047	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3389331-00		70 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Off Label Use; Vomiting	Kaletra			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17753394	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-021569		78 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Long Qt	Azithromycin			S	Unknown	Unk,Not Specified		Aurobindo

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Syndrome	Ceftriaxone	S	Unknown	Unk,Not Specified	Not Reported
	Midazolam	S	Unknown	Unk	Not Reported
	Midazolam	S			Not Reported
	Propofol	S	Unknown	Unk	Not Reported
	Propofol	S			Not Reported
	Dolquine	S	Oral	200 Milligram, Two Times A Day (A Compressed Breakfast And Dinne)	Not Reported
	Kaletra	S	Oral	Unk	Not Reported
	Manidon Hta	C	Unknown	Unk	Not Reported
	Rilast	C	Unknown	Unk	Not Reported
	Omnice Ocas	C	Unknown	Unk	Not Reported
	Simvastatin	C	Unknown	Unk	Not Reported
	Kalpress	C	Unknown	Unk	Not Reported
	Cortic	C	Unknown	Unk,Low Dose Corticoids	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17763611	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1045811		54 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S	Oral	200 Mg/12h		Not Reported
	Hydroxychloroquine			S				Not Reported
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2gr/24h		Mylan
	Ceftriaxona /00672201/			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768365	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597019			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthralgia; C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Joint Swelling; Musculoskeletal Stiffness; Presyncope	Rituximab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Folic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768422	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596002			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Zostavax			S	Intravenous (not otherwise specified)			Not Reported
	Varilrix			S	Intravenous (not otherwise specified)			Not Reported

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	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768496	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3399487-00		70 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronavirus Infection; Diarrhoea; Renal Impairment	Lopinavir/Ritonavir			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Linezolid			C	Intravenous (not otherwise specified)			Not Reported	
	Meropenem			C	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768752	EXPEDITED (15-DAY)		HO	CA-ROCHE-2593341			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Hospitalisation; Infection; Intentional Product Misuse; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Off Label	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Diphenhydramine Hydrochloride;Paracetamol;Phe nylephrine Hydrochloride			S	Unknown			Not Reported	
	Apo-Acetaminophen			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	

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Use; Pain; Pain In Extremity; Peripheral Swelling; Pneumonia; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Therapeutic Product Effect Incomplete; Visual Impairment	Doxycycline	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown	Therapy Duration: 823.0	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Oral	Therapy Duration: 4.0 Months	Not Reported
	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tylenol	S	Unknown		Not Reported
	Synthroid	C			Not Reported
	Methotrexate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768780	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595810		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Ineffective; Gait Inability; Hypoaesthesia; Pharyngeal Oedema; Rash	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768816	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-023990		48 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Cefditoren Pivoxil			S	Oral	400 Milligram, Two Times A Day		Not Reported	
	Cefditoren Pivoxil			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17768910	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246775		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Daily		Sun	
	Plaquenil 200 Mg, Comprime Pellicule			S	Oral	800 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769128	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595786		72 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Unknown			Not Reported	

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Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Folic Acid	C	Unknown	Not Reported
Methotrexate Sodium	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769203	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596166			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Knee Arthroplasty; Nausea; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Other			Not Reported
	Methotrexate			S	Oral			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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		Celebrex		C	Unknown				Not Reported
		Leflunomide		C	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769259	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3399543-00		82 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported	
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported	
	Dolquine			S	Oral			Not Reported	
	Enalapril + Hidroclorotiazida			C	Oral			Not Reported	
	Omeprazol			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769297	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-050486			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Zydus Pharm	
	Plaquenil Sulfate			S	Oral	Unk		Not Reported	
	Lovenox [Enoxaparin Sodium]			C	Oral	Unk		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596822			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituxan	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769515	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596608		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Hepatic Enzyme Abnormal; Pneumonia; Rheumatoid Arthritis; Vomiting	Rituxan			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Loperamide			C				Not Reported
	Pantoprazole			C				Not Reported
	Xeljanz			C				Not Reported
	Align			C				Not Reported
	Actemra			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769595	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596962			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Confusional State; Drug Ineffective; Fall; Headache; Injury; Muscular Weakness; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769616	EXPEDITED (15-DAY)		OT	CA-ADVANS PHARMA- 202004005067			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Diarrhoea; Drug Ineffective; Drug Intolerance; Joint Swelling; Psoriatic Arthropathy; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia
	Methotrexate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			S	Oral	2 G, Qd		Not Reported
	Fish Oil			S	Oral	Unk, Qd		Not Reported
	Inflectra			S	Unknown	5 Mg/Kg Q 0, 2, 6 Weeks		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769657	EXPEDITED (15-DAY)		DE, OT	FR-ADVANS PHARMA- 202004004987			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Death; General Physical Health	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia

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Deterioration; Off Label Use; Tachypnoea	Alfuzosine [Alfuzosin]	C	Unk	Not Reported
	Acetylsalicylic Acid	C	Unk	Not Reported
	Macrogol	C	Unk	Not Reported
	Nebivolol	C	Unk	Not Reported
	Ceftriaxone	C	Unk	Not Reported
	Paracetamol	C	Unk	Not Reported
	Calciparine	C	Unk	Not Reported
	Fresubin	C	Unk	Not Reported
	[Caffelne;Carbohydrates Nos;Fats Nos;Flbre, Dletary;Mlnerals Prednisolone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17769658	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202004004919			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	600 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596364			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Leflunomide	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770068	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004005236			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Myopia; Retinopathy; Systemic Lupus Erythematosus; Visual Acuity Reduced	Hydroxychloroquine			S		600 Mg, Qd		Concordia
	Hydroxychloroquine			S		400 Mg, Qd		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770137	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595745			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous drip			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770159	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES			Unknown	USA

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LIMITED-IPC-2020-US-001362

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Astigmatism; Cornea	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Ipca
Verticillata; Corneal	Hydroxychloroquine			S	Unknown	1200 Milligram, Qd		Ipca
Toxicity; Eyelid Ptosis;	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported
Punctate Keratitis								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770289	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235380		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition	Prednisone			S	Unknown			Actavis
Aggravated;	Methotrexate			S	Unknown			Barr
Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Injection Site	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Bruising; Injection Site	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Erythema; Injection Site								
Pruritus; Injection Site								
Rash; Injection Site								
Reaction; Injection Site	Alendronate Sodium			C	Unknown			Not Reported
Swelling; Joint Swelling;	Fosamax			C	Unknown			Not Reported
Nasopharyngitis;	Ibuprofen			C	Unknown			Not Reported
Rheumatoid Arthritis;	Lisinopril			C	Unknown			Not Reported
Suicidal Ideation	Vitamin D3			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770291	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234164			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Mood Altered; Rheumatoid Arthritis	Methotrexate	S	Unknown	Barr
	Prednisone	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770292	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1234235			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Dehydration; Drug Ineffective	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770293	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235381		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Disorder; Eye Pain; Fatigue; Glaucoma; Inflammation; Lacrimation Increased; Pain; Photophobia; Post Procedural Complication;	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Subcutaneous			Barr
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Rheumatoid Arthritis; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770303	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596964		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Infusion Related Reaction; Off Label Use; Pharyngeal Swelling; Poor Venous Access; Vasculitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Epinephrine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fentanyl			C				Not Reported
	Losartan			C				Not Reported
	Mirtazapine			C				Not Reported
	Progesterone			C				Not Reported
	Rabeprazole			C				Not Reported
Sertraline			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770331	EXPEDITED (15-DAY)		HO, LT, OT	JP-ACCORD-181070		41 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Disorder; Exposure During Pregnancy; Hormone Level Abnormal; Hypogonadism; Infarction; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Tacrolimus			S				Accord
	Estradiol			S	Transdermal			Not Reported
	Progesterone			S	Vaginal			Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Prednisolone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770353	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235370		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770367	DIRECT	Y	HO, OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tachyarrhythmia	Hydroxychloroquine			S	Oral			Not Reported	
	Azithromycin 500mg Daily			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770369	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597007			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Back Injury; Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Injury; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cimzia	C	Subcutaneous	Not Reported
Enbrel	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596382		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Hypertensive Crisis; Presyncope; Treatment Failure	Rituximab			S	Unknown	Therapy Duration: 7.0 Years		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported
	Folic Acid			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770677	DIRECT	Y	HO, OT			85 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Electrocardiogram Qt Prolonged; Ventricular Extrasystoles	Hydroxychloroquine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770905	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020185534		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
Electrocardiogram Qt Prolonged; Off Label Use;	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
Product Use In Unapproved Indication; Product Use Issue	Rocephine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770950	EXPEDITED (15-DAY)		OT	CA-SA-2019SA057628		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue;	Arava			S	Unknown	20 Mg		Sanofi
Leukopenia; Nausea;	Hydroxychloroquine Sulfate			S	Unknown	300.0 Mg, Unk		Sanofi
Treatment Failure;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
Vomiting; Weight Decreased	Hydroxychloroquine Sulfate			S	Unknown	200 Mg		Sanofi
	Methotrexate			S	Unknown	15.0 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771123	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1045657		78 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
Electrocardiogram Qt Prolonged	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771147	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595696		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Body Height Decreased; Contraindicated Product Administered; Drug Ineffective; Flushing; Inflammation; Interstitial Lung Disease; Rheumatoid Arthritis	Rituxan			S	Intravenous drip			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Orencia			S	Unknown	3.0 Months		Not Reported
	Methotrexate			S	Unknown	366.0		Not Reported
	Arava			S	Unknown	366.0		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	366.0		Not Reported
	Lyrica			S	Unknown	366.0		Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Lumigan Rc			C	Ophthalmic			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported
	Tylenol Extra Strength			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771350	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA- 202004004924			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Aspartate	Hydroxychloroquine	S	200 Mg, Bid	Concordia
Aminotransferase Increased; Bilirubin Conjugated Abnormal; Blood Creatinine Increased; Death; Off Label Use	Hydroxychloroquine	S		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771351	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004004723			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Macular Degeneration; Toxicity To Various Agents	Hydroxychloroquine			S		Unk, Duration For Less Than 3 And Half Yeas		Concordia	
	Prednisone			S		Unk,10 To 20 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771443	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045786		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	C/24 H		Not Reported	
	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Ertapenem			S	Intravenous (not otherwise specified)	1 G Dia		Mylan	
	Dolquine			S	Oral	400 Mg Dia		Mylan	
	Dolquine			S				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771446	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045819		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Mg Dia		Not Reported	

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Azithromycin	S				Not Reported
Ceftriaxona /00672201/	S	Intravenous (not otherwise specified)	2 G Dia		Mylan
Ceftriaxona /00672201/	S				Mylan
Dolquine	S	Oral	400 Mg Dia		Mylan
Dolquine	S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590775		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Anti-Cyclic Citrullinated	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
Peptide Antibody; C-Reactive Protein	Adalimumab			S	Subcutaneous			Not Reported
Increased;	Enbrel			S	Unknown			Not Reported
Contraindicated Product	Leflunomide			S	Oral			Not Reported
Administered; Drug	Orencia			S	Subcutaneous			Not Reported
Ineffective; Joint Swelling;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Leukopenia;	Gold			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Humira			S	Subcutaneous			Not Reported
Pain; Rash; Rheumatoid	Humira			S	Subcutaneous			Not Reported
Arthritis; Rheumatoid	Sodium Aurothiomalate			S	Unknown			Not Reported
Factor Positive; Swelling;	Acetaminophen			C				Not Reported
Therapeutic Product Effect	Depo-Medrol			C	Intra-articular			Not Reported
Decreased; Therapeutic	Methotrexate			C	Subcutaneous			Not Reported
Product Effect Incomplete;	Methotrexate			C	Subcutaneous			Not Reported
Toxicity To Various	Methotrexate			C	Unknown			Not Reported
Agents; Visual Impairment	Methotrexate			C	Unknown			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported

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Prednisone	C	Unknown	Not Reported
Sulfasalazine	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771612	EXPEDITED (15-DAY)		HO, LT	ES-PFIZER INC-2020187944		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Off Label Use; Pancreatitis Acute; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	250 Mg, 1x/Day		Pfizer	
	Kaletra			S	Oral	2 Df, 2x/Day (Every 12 Hours)		Not Reported	
	Ceftriaxon			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported	
	Dolquine			S	Oral	200 Mg, 2x/Day (Every 12 Hours)		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771649	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2591841		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe (Subcutaneous Solution)		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported	

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Independence In Daily Activities; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution (Intravenous)	Not Reported
	Simponi	S	Subcutaneous	Subcutaneous Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771827	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2020185943		76 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Norvasc			S	Oral	10 Mg, 1x/Day		Pfizer	
	Norvasc			S		Unk (Reduced Dose)		Pfizer	
	Ritonavir			S	Oral	100 Mg, 1x/Day		Not Reported	
	Clexane T			S	Subcutaneous	6000 Kiu, 1x/Day		Not Reported	
	Darunavir			S	Oral	800 Mg, 1x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported	
	Azithromycin Teva			S	Oral	500 Mg, 1x/Day		Not Reported	
	Eutirox			C		Unk		Not Reported	
	Folifill			C		Unk		Not Reported	
	Ceftriaxone			C	Oral	1 Df, 1x/Day		Not Reported	
	Lasix [Furosemide]			C		Unk		Not Reported	
	Urbason Solub			C	Intravenous (not otherwise specified)	1 Df, 1x/Day		Not Reported	
	Omeprazole			C		Unk		Not Reported	

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Trelegy Ellipta			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17772487	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20200512027			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Darunavir			S	Unknown			Janssen	
	Hydroxychloroquine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17773499	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3399921-00		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rash Pruritic	Kaletra 200/50			S	Oral			Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported	
	Hidroxyclozoquina Sulfato			S	Oral			Not Reported	
	Azitromicina			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17773527	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-024316		72 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Meropenem			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo	
	Piperacillin+Tazobactam 4.5g			S	Intravenous (not otherwise specified)	1 Dosage Form, 3 Times A Day		Aurobindo	
	Linezolid			S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day		Aurobindo	
	Roactemra			S	Unknown	600 Milligram,1 Total		Not Reported	
	Roactemra			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metamizole	S	Intravenous (not otherwise specified)	2 Gram, 3 Times A Day	Not Reported
Hydroxychloroquine	S	Oral	400 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17773531	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2020-024317		83 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Hydroxychloroquine Phosphate			S	Oral	400 Milligram, Once A Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2 Dosage Form, 3 Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	11176748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1589866		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspepsia; Liver Function Test Abnormal; Liver Function Test Increased; Liver Function Test Increased; Nausea; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Response Decreased	Rituxan			S	Intravenous (not otherwise specified)	Discontinued After 2 Cycles, Therapy Duration: 4 Months.		Not Reported
	Humira			S	Subcutaneous	For 4 Years		Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 8 Years		Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arava	S	Oral	Therapy Duration: 4 Months	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 6 Months	Not Reported
Tofacitinib	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	12678680	EXPEDITED (15-DAY)		OT	CA-ROCHE-1817079		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Rituxan			S	Intravenous drip			Not Reported
Cataract; Contraindicated	Sulfasalazine			S	Oral			Not Reported
Product Administered;	Celebrex			S	Oral			Not Reported
Drug Ineffective;	Arava			S	Unknown			Not Reported
Laboratory Test Abnormal;	Arava			S	Unknown			Not Reported
Red Blood Cell Sedimentation Rate Abnormal	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	12884262	EXPEDITED (15-DAY)		OT	CA-ROCHE-1734356		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction;	Actemra			S	Unknown	Discontinued		Not Reported	
Arthralgia; Condition	Enbrel			S	Unknown	Discontinued		Not Reported	
Aggravated;	Orencia			S	Unknown	Discontinued		Not Reported	
Contraindicated Product	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
Administered; Drug	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
Ineffective; Joint Swelling;	Methotrexate Sodium			S	Unknown			Not Reported	
Musculoskeletal Disorder;	Arava			S	Unknown	Therapy Duration: 4 Months		Not Reported	
Nasopharyngitis;	Xeljanz			S	Oral			Not Reported	
Neutropenia; Platelet	Xeljanz			S	Oral			Not Reported	
Count Decreased;	Xeljanz			S	Oral			Not Reported	
Respiratory Tract Infection	Xeljanz			S	Oral			Not Reported	
Viral; Rheumatoid Arthritis;	Hydroxychloroquine			S	Unknown			Not Reported	
Sinusitis; Skin Papilloma;	Apo-Leflunomide			S	Unknown			Not Reported	
Sleep Disorder; Tendon	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Disorder;	Leflunomide			C	Unknown			Not Reported	
Thrombocytopenia	Prednisone			C				Not Reported	
	Folic Acid			C				Not Reported	
	Naproxen			C				Not Reported	
	Advil [Ibuprofen]			C				Not Reported	
	Ketorolac			C				Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported	
	Methotrexate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	12988986	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ROCHE-1860198			Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Actemra			S	Unknown			Not Reported
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product	Anakinra			S	Unknown			Not Reported
Administered; Deep Vein Thrombosis; Diverticulitis;	Humira			S	Subcutaneous			Not Reported
Drug Hypersensitivity;	Hydroxychloroquine			S	Unknown			Not Reported
Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure;	Leflunomide			S	Oral			Not Reported
Sepsis; Stomatitis; Terminal State;	Methotrexate Sodium			S	Unknown			Not Reported
Thrombosis; Urticaria	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Marijuana			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Arava			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

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Ilaris	S	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	13203126	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889218		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Operation;	Rituxan			S	Unknown			Not Reported
Arthralgia; Arthropathy;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Cyclical		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	13281112	EXPEDITED (15-DAY)		OT	CA-ROCHE-1898409		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Drug Ineffective; Drug	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Abatacept			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Drug	Arava	S	Oral		Not Reported
Resistance; Fatigue; Gait	Golimumab	S	Unknown		Not Reported
Disturbance; Inflammation;	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Mouth Ulceration; Pain;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Peripheral Swelling;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rheumatoid Arthritis;	Methotrexate Sodium	S	Unknown		Not Reported
Rotator Cuff Syndrome;	Methotrexate Sodium	S	Unknown		Not Reported
Swelling; Therapeutic	Sulfasalazine	S	Unknown		Not Reported
Response Decreased;	Nystatin	S	Unknown		Not Reported
Tongue Ulceration; Tooth	Nystatin	S	Unknown		Not Reported
Infection; Treatment	Prednisone	C	Unknown		Not Reported
Failure	Tramadol	C	Unknown		Not Reported
	Indocine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	13842763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1973086			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Adverse Event;	Rituxan			S	Intravenous (not			Not Reported
Alopecia; Bronchitis					otherwise specified)			
Chronic; Contraindicated	Actemra			S	Unknown			Not Reported
Product Administered;	Humira			S	Subcutaneous			Not Reported
Drug Hypersensitivity;	Enbrel			S	Unknown			Not Reported
Drug Ineffective; Drug	Methotrexate Sodium			S	Unknown			Not Reported
Intolerance; General	Remicade			S	Intravenous (not			Not Reported
Symptom; Neck Pain;					otherwise specified)			
Neck Surgery; Off Label	Remicade			S	Intravenous (not			Not Reported
Use; Rheumatoid Factor					otherwise specified)			
Positive; Spinal Column	Orencia			S	Unknown			Not Reported
Injury; Surgical Failure;	Arava			S	Unknown			Not Reported
Synovitis; Treatment								
Failure								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arava	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Rituxan	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Mobicox	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	15364714	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2181752		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Blood Creatine Decreased; Condition Aggravated; Drug Ineffective; Drug Intolerance; Eye Discharge; Eye Disorder; Eye Operation; Eye Pain; Fatigue; Glaucoma; Haematocrit Decreased; Haemoglobin Decreased; Headache; Inflammation; Lacrimation Increased; Lymphocyte Count Increased; Monocyte Count Increased; Nasopharyngitis; Nausea; Neutrophil Count	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo Hydromorphone			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Ocular	Hydroxychloroquine	S	Unknown	Not Reported
Procedural Complication;	Hydroxychloroquine	S	Unknown	Not Reported
Optic Neuritis; Pain;	Hydroxychloroquine	S	Unknown	Not Reported
Photophobia; Post	Hydroxychloroquine	S	Unknown	Not Reported
Procedural Complication;	Hydroxychloroquine	S	Unknown	Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown	Not Reported
Synovitis; Therapeutic	Hydroxychloroquine	S	Unknown	Not Reported
Product Effect Decreased;	Methotrexate	S	Subcutaneous	Not Reported
Tinnitus; Vision Blurred;	Methotrexate	S	Subcutaneous	Not Reported
White Blood Cell Count	Methotrexate	S	Subcutaneous	Not Reported
Decreased	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Acetaminophen	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Alendronate	C	Unknown	Not Reported
	Sodium;Calecalciferol			
	Alendronate	C	Unknown	Not Reported
	Sodium;Calecalciferol			
	Humira	C	Unknown	Not Reported
	Hydrocortisone	C	Nasal	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Hyzaar	C	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Remicade	C	Unknown	Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	15402622	EXPEDITED (15-DAY)		HO, OT	CO-ACTELION-A-CH2018-179017		63 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Tracleer			S	Oral	62.5 Mg, Bid		Actelion
Abdominal Pain Upper;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Acute Oesophageal	Opsumit			S	Oral	10 Mg, Od		Actelion
Mucosal Lesion; Angina	Opsumit			S	Oral	10 Mg, Od		Actelion
Unstable; Anxiety;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Arrhythmia; Asthenopia;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Blood Creatinine	Opsumit			S	Oral	10 Mg, Qd		Actelion
Increased; Bronchitis;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Cardiac Failure; Chest	Opsumit			S	Oral	10 Mg, Qd		Actelion
Discomfort; Chest Pain;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Choking; Chronic Kidney	Riociguat			S	Unknown	Unk		Not Reported
Disease; Coagulation	Hidroxicloroquina			S	Unknown			Not Reported
Time Prolonged;	Levetiracetam			S	Unknown			Not Reported
Coagulopathy;	Carvedilol			C				Not Reported
Constipation; Diarrhoea;								
Discomfort; Dizziness;								
Dyspnoea; Ear Disorder;								
Eye Disorder; Fall;								
Fatigue; Feeling								
Abnormal; Fibromyalgia;								
Flatulence; Fluid								
Retention; Gait								
Disturbance; General								
Physical Health								
Deterioration;								
Haematemesis; Head								
Discomfort; Headache;								
Heart Disease Congenital;								
Hyponatraemia;								
Hypotension;								
Hysterectomy;								
Inflammation;								
Inflammation Of Wound;								
Intestinal Obstruction;								
Joint Swelling; Loss Of								
Control Of Legs; Malaise;								

FDA Adverse Event Reporting System

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Memory Impairment; Mitral
Valve Calcification; Mitral
Valve Disease;
Musculoskeletal Pain;
Nervous System Disorder;
Pain In Extremity;
Peripheral Swelling;
Product Availability Issue;
Pulmonary Artery
Occlusion; Reflux
Gastritis; Renal Disorder;
Swelling Face; Swelling Of
Eyelid; Syncope; Tremor;
Vasodilatation; Walking
Aid User; Walking
Disability; Wheelchair
User

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	15843027	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20190118848		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Arthroplasty;	Simponi			S	Subcutaneous			Janssen
Arthropathy;	Remicade			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Drug								
Ineffective; Foot	Remicade			S				Not Reported
Deformity; Foot Operation;	Enbrel			S	Unknown			Not Reported
Infection; Limb Discomfort;	Enbrel			S				Not Reported
Loss Of Consciousness;	Actemra			S	Unknown			Not Reported
Malaise; Mobility								
Decreased; Nausea;	Actemra			S				Not Reported
Nodule; Off Label Use;	Anakinra			S	Unknown			Not Reported
Rheumatoid Arthritis								
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported
					otherwise specified)			

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Risedronate Sodium	S	Unknown	Not Reported
Risedronate Sodium	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Actonel	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Risedronic Acid	S	Unknown	Not Reported
Hydroxychloroquine	C	Oral	Not Reported
Hydroxychloroquine	C		Not Reported
Risedronate	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	16046574	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057903		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Drug Ineffective; Exostosis; Osteoarthritis; Pain In Extremity; Pulmonary Thrombosis; Thrombosis	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Plaquenil			S	Unknown	Unk Unk, Bid		Sanofi
	Pantoprazole			C	Unknown	40 Mg, Qd		Not Reported
	Pravastatin			C	Unknown	40 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	16055947	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA057819		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Arava			S	Oral	20 Mg, Qd		Sanofi
Blood Creatinine	Gabapentin			S	Unknown	Unk		Not Reported
Increased; Blood	Gabapentin			S	Unknown	100 Mg, Unk		Not Reported
Magnesium Increased;	Celecoxib			S	Oral	Unk		Not Reported
Blood Potassium	Celecoxib			S	Oral	Unk		Not Reported
Increased; Bone Cyst;	Fentanyl			S	Unknown	Unk		Not Reported
Crohn'S Disease; Cyst;	Oxycodone			S	Unknown	Unk		Not Reported
Deafness Neurosensory;	Plaquenil			S	Unknown	400 Mg, Qd		Sanofi
Deformity; Diarrhoea;	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
Drug Hypersensitivity;	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Sanofi
Drug Ineffective; Drug	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
Intolerance; Dry Eye;	Myochrysine			S	Intramuscular	50 Mg, Q3w		Not Reported
Epigastric Discomfort;	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
Exostosis; Fatigue;	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Qm		Not Reported
Gastrointestinal Disorder;	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Qm		Not Reported
Hospitalisation;	Omega 3 [Fish Oil]			C	Oral	1200 Mg, Bid		Not Reported
Hypersensitivity; Infection;	Omega 3 [Fish Oil]			C	Unknown	Unk		Not Reported
Joint Swelling; Mobility	Aclasta			C	Intravenous (not otherwise specified)	750 Mg, Unk		Not Reported
Decreased;	Actonel			C	Unknown	36 Mg, Qw		Not Reported
Musculoskeletal Stiffness;	Ascorbic Acid			C	Unknown	Unk		Not Reported
Myocardial Infarction;	Biotin			C	Unknown	Unk		Not Reported
Nausea; Osteoarthritis;	Calcium			C	Unknown	Unk		Not Reported
Osteopenia;								
Osteosclerosis; Pain; Pain								
In Extremity; Pleural								
Fibrosis; Pleural								
Thickening; Presbycusis;								
Renal Impairment;								
Rheumatoid Arthritis; Skin								
Lesion; Sleep Disorder;								
Therapeutic Product Effect								
Decreased; Treatment								
Failure; Unevaluable								
Event; Unevaluable Event								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg	Not Reported
Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Mg, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
Fish Oil	C	Unknown	1200 Mg, Bid	Not Reported
Genteal [Hypromellose]	C	Unknown	Unk	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
Nasonex	C	Unknown	Unk	Not Reported
Nexium [Esomeprazole Magnesium]	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk Unk, Bid	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Mg, Qcy	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Unk	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	400 Mg, Qd	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Sodium	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Trazodone [Trazodone Hydrochloride]	C	Oral	50 Mg, Qcy	Not Reported
Tylenol [Paracetamol]	C	Unknown	50 Mg, Qcy	Not Reported
Vit D3	C	Unknown	Unk	Not Reported
Vitamin A [Retinol]	C	Unknown	Unk	Not Reported
Vitamin B12 [Vitamin B12 Nos]	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D [Vitamin D Nos]	C	Unknown	400 Df, Qd	Not Reported
Xeljanz	C	Oral	5 Mg, Qd	Not Reported
Thiamine Hcl	C			Not Reported
Oxycodone And Acetaminophen	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	16341891	EXPEDITED (15-DAY)		HO, OT	US-VALIDUS PHARMACEUTICALS LLC-US- 2019VAL000245			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Coronary Artery Occlusion; Diabetes Mellitus; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Furosemide			S	Unknown	Unk		Validus
	Nifedipine			S	Unknown	Unk		Validus
	Famotidine			S	Unknown	Unk		Not Reported
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported
	Trandolapril			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Plavix			S	Unknown	Unk		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	Unk		Not Reported
	Glyceryl Trinitrate			S	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk		Not Reported
	Trazodone Hydrochloride			S	Unknown	Unk		Not Reported
	Loperamide Hydrochloride			S	Unknown	Unk		Not Reported
	Ambien			S	Unknown	Unk		Not Reported
	Gabapentin			S	Unknown	Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk		Not Reported
	Flomax /00889901/			S	Unknown	Unk		Not Reported
	Isosorbide Mononitrate			S	Unknown	Unk		Not Reported
	Potassium Acetate			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Doxycycline Hyclate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	16388022	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR- APL-2019-029850		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Confusional State; Contusion; Fall; Fatigue; Grip Strength Decreased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Osteoarthritis; Pain; Rheumatoid Arthritis; Rotator Cuff Repair; Spinal Stenosis; Tenderness; Treatment Failure	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Lisinopril Tablet			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Diclofenac			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Diclofenac			S	Oral	75 Milligram, As Necessary		Not Reported
	Diclofenac			S	Oral	Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	20 Milligram, Every Week		Not Reported
	Plaquenil			S	Oral	200 Milligram, Once A Day		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Oral	2 Gram, Once A Day		Not Reported
	Sulfasalazine			S	Oral	1 Gram, Two Times A Day		Not Reported
	Sulfasalazine			S	Oral	500 Milligram, Once A Day		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Tecta			S	Oral	Unk		Not Reported
	Xeljanz			S	Oral	10 Milligram, Once A Day		Not Reported
	Voltaren			S	Oral	75 Milligram, Two Times A Day		Not Reported
	Voltaren			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Folic Acid	S	Unknown	Unk	Not Reported
Apo-Diclofenac	S	Oral	75 Milligram, Two Times A Day	Not Reported
Apo-Diclofenac	S	Oral	75 Milligram	Not Reported
Apo-Lisinopril	S	Unknown	Unk	Not Reported
Depo-Medrol	C	Intramuscular	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	16740198	EXPEDITED (15-DAY)		OT	DE-DRREDDYS-GER/GER/19/0113518			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S				Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Omeprazole			S		20 Mg, Bid		Not Reported
	Sildenafil			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1-0-1)		Not Reported
	Spasmolyt			S		1 Df, Qd (1-0-1)		Not Reported
	Spasmolyt			S	Unknown	30 Mg (0 -0 -1)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
Ambrisentan	S	Unknown		Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Ambrisentan	S	Unknown		Not Reported
Ambrisentan	S			Not Reported
Lyrice	S	Unknown	100 Milligram, Tid	Not Reported
Lyrice	S	Unknown	100 Milligram, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17024666	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459897			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthralgia; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Joint Stiffness; Liver Function Test Abnormal; Mobility Decreased; Pneumonia; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Bifidobacterium Bifidum			C	Unknown			Not Reported
	Loperamide			C	Oral			Not Reported
	Pantoprazole			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17046117	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2465588		58 YR	Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Death; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Rheumatoid Arthritis; Sepsis; Stomatitis; Terminal State; Thrombosis; Urticaria	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous	Single-Use Vial: Powder For Solution For Injection		Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfate] Remicade	S	Intravenous (not otherwise specified)	Powder For Solution For Infusion	Not Reported
Remicade	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Arava	S			Not Reported
Cannabis Sativa	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Parenteral		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Rituximab	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Anakinra	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17114110	EXPEDITED (15-DAY)		OT	CA-SA-2019SA336230			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown	Unk		Not Reported
Alopecia; Arthropathy;	Desoximetasone			S	Oral	Unk		Sanofi
Contraindicated Product	Arava			S	Oral	Unk		Sanofi
Administered; Discomfort;	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Drug Ineffective; Fatigue;	Folic Acid			S	Unknown	Unk (Not Specified (1 Mg)		Not Reported
Glossodynia; Hand	Alendronate Sodium			S	Unknown	Unk		Not Reported
Deformity; Infusion	Hydroxychloroquine			S	Oral	Unk		Sanofi
Related Reaction;	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 1 In 1 D		Sanofi
Maternal Exposure During								
Pregnancy; Pain;								
Pemphigus; Product Use								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate	S	Intra-arterial	25 Mg, Qd	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 G	Not Reported
	Sulfasalazine	S	Unknown	2 Gm (1 Gm,1 In 12 H)	Not Reported
	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
	Cimzia	S	Subcutaneous	Unk (Single-Use Prefilled Syringe)	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Phosphate	S	Unknown	400 Mg, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17407151	EXPEDITED (15-DAY)		OT	CA-ROCHE-1698470		36 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Disease Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia;	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Months		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To A General Medical Condition	Arava	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	5.0 Months	Not Reported
	Gold	S	Unknown	7.0 Months	Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	3.0 Years	Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17416504	EXPEDITED (15-DAY)		HO	US-ACTELION-A-US2020-201797		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacteraemia; Blood Culture Positive; Brevibacterium Infection; Catheter Management; Catheter Site Infection; Device Related Infection; Diarrhoea; Dyspnoea Exertional; Ear Infection; Immunosuppression; Sepsis	Opsumit			S	Oral	10 Mg, Qd		Actelion	
	Velettri			S	Intravenous (not otherwise specified)	28 Ng/Kg, Per Min		Actelion	
	Plaquenil			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Letairis			C				Not Reported	
	Xarelto			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17492232	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201703-001950			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Condition Aggravated; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Arava			S	Oral	Unk Unk, Weekly		Not Reported
	Sodium Aurothiomalate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	640 Mg, Weekly		Not Reported
	Actemra			S	Unknown	640 Unk		Not Reported
	Actemra			S	Unknown	640 Unk		Not Reported
	Apo-Cyclosporine			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Weekly		Not Reported
	Cimzia			S	Subcutaneous	Unk Single-Use Prefilled Syringe		Not Reported
	Enbrel			S		50 Mg, Weekly		Not Reported
	Enbrel			S	Unknown	50 Unk		Not Reported
	Enbrel			S	Unknown	50 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Humira			S	Unknown	40 Unk		Not Reported
	Humira			S	Unknown	40 Mg, Weekly		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Weekly		Not Reported
Sulfasalazine			S	Unknown	Unk		Not Reported	
Certolizumab			S	Subcutaneous	200 Mg, Weekly		Not Reported	
Certolizumab			S	Unknown	200 Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Certolizumab	S	Unknown	200 Mg	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Gold	S	Unknown	Unk	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	300 Mg, Weekly	Not Reported
Infliximab	S	Unknown	300 Mg, Weekly	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Ciclosporin	S	Oral	Unk	Not Reported
Prednisone	C		Unk	Not Reported
Piroxicam	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17558038	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318943		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Off Label Use; Pain; Rheumatic Fever; Rheumatoid Arthritis; Spinal Stenosis; Synovitis; Therapeutic Product Effect Decreased; Treatment	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Failure; Type 2 Diabetes Mellitus; Unevaluable Event; Urinary Tract Infection	Actemra	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Topicort /00028604/	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Plaquenil /00072602/	S	Oral	Not Reported
	Celebrex	C	Unknown	Not Reported
	Gold	C		Not Reported
	Morphine	C	Unknown	Not Reported
	Tofacitinib	C	Oral	Not Reported
	Acetaminophen W/Dextropropoxyphene	C		Not Reported
	Desoximetason	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17586718	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015347561		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Dyspnoea; Lower Respiratory Tract Infection; Pain	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Arava			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17644416	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA-202003002706			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Off Label Use; Pulmonary Embolism; Respiratory Failure; Septic	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
	Morphine			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Shock

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17655387	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3357377-00		76 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Ventricular Tachycardia	Kaletra			S	Oral				Not Reported
	Plaquenil			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17667419	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200409451		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Simponi			S	Subcutaneous				Janssen
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Remicade			S	Intravenous (not otherwise specified)	Cyclical			Janssen
Arthralgia; Arthropathy;	Actemra			S	Subcutaneous				Not Reported
Blister; Confusional State; Contraindicated Product Administered; Contusion;	Actemra			S	Intravenous (not otherwise specified)				Not Reported
Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation;	Actemra			S	Intravenous (not otherwise specified)				Not Reported
Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Glossodynia;	Actemra			S	Intravenous (not otherwise specified)				Not Reported
Hand Deformity;	Chloraprep			S		Topical			Not Reported
Helicobacter Infection;	Chlorhexidine Gluconate			S	Unknown	Oral Rinse			Not Reported
Hepatic Enzyme Increased;	Cimzia			S	Subcutaneous				Not Reported
Hypersensitivity; Ill-Defined Disorder;	Enbrel			S	Subcutaneous				Not Reported
Impaired Healing;	Enbrel			S	Subcutaneous				Not Reported
Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling;	Hydroxychloroquine			S	Oral				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Pain; Pemphigus; Pericarditis; Peripheral Swelling; Pregnancy; Pruritus; Pyrexia; Rash; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Weight Increased; Wound	Leflunomide	S	Oral		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Oxycodone	S			Not Reported
	Oxycodone Hydrochloride	S			Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Oxycodone And Acetaminophen	S	Unknown		Not Reported
	Periogard	S	Buccal	Alcohol Free	Not Reported
	Sulfamethoxazole	S			Not Reported
	Sulfamethoxazole And Trimethoprim	S			Not Reported
	Arava	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Cetirizine	S	Unknown		Not Reported
	Cetirizine Hydrochloride W/Pseudoephedrine Hy	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Plaquenil /00072602/	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Cortisone	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topicort /00028604/	S	Cutaneous	Not Reported
Chlorhexidine	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Cetirizine Hydrochloride	C		Not Reported
Desogestrel And Ethinylestradiol	C		Not Reported
Ibuprofen	C		Not Reported
Pantoloc /01263201/	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Paracetamol/Codeine	C		Not Reported
Reactine /00884302/	C		Not Reported
Tylenol /00020001/	C		Not Reported
Tylenol With Codeine	C		Not Reported
Atasol /00020001/	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17678265	EXPEDITED (15-DAY)		OT	US-ADVANS PHARMA-202004002747			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation;	Hydroxychloroquine			S	Unknown	400 Mg, Bid		Concordia	
Electrocardiogram Qrs	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia	
Complex Prolonged;	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported	
Electrocardiogram Qt	Apixaban			C		5 Mg, Bid		Not Reported	
Prolonged; Off Label Use	Metoprolol Succinate			C		25 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Flecainide	C	50 Mg, Bid	Not Reported
Flecainide	C	100 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17688626	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA-202004002981			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acidosis; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Infection; Inflammation; Off Label Use; Pyrexia; Respiratory Disorder	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1200 Mg, Qd		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 MI, Qd		Not Reported
	Midazolam			S	Intravenous (not otherwise specified)	5 Milligram Per Millilitre, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	20 Mg, Qd		Not Reported
	Omeprazole			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	30 Mg, Qd		Not Reported
	Movicol			S		2 Dosage Form Bag		Not Reported
	Paracetamol			C		Unk		Not Reported
	Paracetamol			C				Not Reported
	Lasilix			C		Unk		Not Reported
	Novorapid			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17726014	EXPEDITED (15-DAY)		OT	NVSC2020CA115075		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>



Detailed Report

Abdominal Discomfort;	Diclofenac	S	Unknown	Unk	Novartis
Adverse Drug Reaction;	Methotrexate	S	Oral	25 Mg	Not Reported
Alopecia; Anti-Cyclic	Methotrexate	S	Oral	25 Mg	Not Reported
Citrullinated Peptide	Methotrexate	S	Oral	25 Mg, Qw	Not Reported
Antibody Positive;	Leflunomide	S	Unknown	Unk	Not Reported
Arthralgia; Discomfort;	Folic Acid	S	Unknown	5 Mg	Not Reported
Drug Ineffective; Drug	Folic Acid	S	Oral	25 Mg	Not Reported
Intolerance; Fatigue;	Pseudoephedrine Hcl	S	Unknown	Unk	Not Reported
Glossodynia; Hand	Cetirizine Hydrochloride	S	Unknown	10 Mg	Not Reported
Deformity; Hepatic	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Enzyme Increased;	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
Hypersensitivity; Infusion	Cortisone Acetate	S	Unknown	25 Mg	Not Reported
Related Reaction; Joint	Topicort	S	Subcutaneous	Unk	Not Reported
Swelling; Maternal	Topicort	S	Topical	Unk	Not Reported
Exposure During	Desoximetasone	S	Oral	Unk	Not Reported
Pregnancy;	Stelara	S	Subcutaneous	Unk	Not Reported
Musculoskeletal Stiffness;	Cimzia	S	Subcutaneous	400 Mg	Not Reported
Off Label Use; Pain;	Simponi	S	Subcutaneous	Unk	Not Reported
Pemphigus; Pericarditis;	Remicade	S	Subcutaneous	Unk	Not Reported
Product Use Issue; Rash;	Enbrel	S	Subcutaneous	Unk	Not Reported
Rheumatoid Arthritis;	Fosamax	S	Oral	Unk	Not Reported
Rheumatoid Factor	Fosamax	S	Oral	Unk	Not Reported
Positive; Synovitis;	Fosamax	S	Oral	Unk	Not Reported
Systemic Lupus	Humira	S	Subcutaneous	4 Mg	Not Reported
Erythematosis;	Humira	S	Unknown	400 Mg	Not Reported
Therapeutic Product Effect	Orencia	S	Subcutaneous	Unk	Not Reported
Decreased; Treatment	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Failure; Wound	Plaquenil	S	Unknown	400 Mg, Qd	Not Reported

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Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G, Bid	Not Reported
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	5 Mg, Qd	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
Apo-Hydroxyquine	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	Unk	Not Reported
Apo-Prednisone	S	Unknown	40 Mg	Not Reported
Arava	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17729389	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436797			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Mefenamic Acid	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Tylenol /00020001/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17730576	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437119		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Leukopenia; Mouth Ulceration; Patient Dissatisfaction With Treatment	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Azathioprine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17743411	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437155			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17743416	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437389		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17743421	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437443			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Enbrel			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Neoral			S	Oral			Not Reported	
	Plaquenil /00072602/			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17743424	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437159		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankle Operation; Arthralgia; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Anakinra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17743985	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437137		65 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cerebrovascular Accident; Drug Ineffective; Eye Disorder; Gait Inability; Headache; Herpes Zoster; Joint Swelling; Rheumatoid Arthritis; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Asprin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17743992	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200437152		24 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Injection Site Reaction; Joint Swelling;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17744189	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436841		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Sounds Abnormal; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Asa			C				Not Reported
	Bisoprolol Fumarate			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metformin	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Paroxetine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported
Simvastatin	C	Unknown	Not Reported
Statex /00036302/	C	Unknown	Not Reported
Telmisartan	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17747073	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437411			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Ineffective; Goitre; Headache; Inflammation; Joint Swelling; Knee Arthroplasty; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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Citalopram Hydrobromide	C	Unknown	Not Reported
Ketoprofen	C		Not Reported
Naproxen	C		Not Reported
Omeprazole	C		Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Rosuvastatin Calcium	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17747079	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200437399		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Disability; Drug Ineffective; Hepatic Enzyme Increased; Ileostomy; Intestinal Obstruction; Musculoskeletal Stiffness; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Therapy Non-Responder; Wheelchair User	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17747149	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437147		57 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported
	Canakinumab			C	Subcutaneous	Powder For Solution		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17747156	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437151		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Chronic Kidney Disease; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported

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Lung Disease; Synovitis; Systemic Lupus Erythematosis; Treatment Failure	Clavulin /00756801/	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tocilizumab	S	Unknown	Not Reported
	Plaquenil /00072603/	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17747157	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200437139		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown			Not Reported
	Advil /00109201/			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac /01001802/			C	Unknown			Not Reported

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Leflunomide	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17747993	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200437162		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Hospitalisation; Infection; Rash; Rheumatoid Arthritis; Urticaria	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Amlodipine			C				Not Reported
	Benadryl /00000402/			C				Not Reported
	Arava			C				Not Reported
	Naproxen			C	Unknown			Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C	Unknown			Not Reported
	Viread			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17751807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010411			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C	Unknown	Unk		Not Reported
	Sulfasalazine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17757930	EXPEDITED (15-DAY)		LT, OT	JP-BAUSCH-BL-2020-013339		41 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Normal Newborn; Placenta Accreta	Prednisolone			S	Unknown			Not Reported
	Prednisolone			S	Unknown	Increased Dose		Not Reported
	Estradiol			S	Transdermal	Until 10 Weeks Of Gestation		Not Reported
	Tacrolimus Hydrate			S	Unknown			Not Reported
	Progesterone			S	Vaginal	Until 10 Weeks Of Gestation		Not Reported
	Dydrogesterone			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Oxytocin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773117	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-023950		66 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Aurobindo
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Loxen (Nicardipine Hydrochloride)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Sufentanil			C	Unknown	Unk		Not Reported
	Nimbex			C	Unknown	Unk		Not Reported
	Hypnovel			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773297	EXPEDITED (15-DAY)		DE, OT	MX-ADVANSZ PHARMA- 202004004918			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Norepinephrine			C		Unk		Not Reported
	Ceftazidime			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Trimethopim Sulfamethoxazole			C		Unk		Not Reported
	Lineozlid			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595675		66 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Cough; Drug Ineffective; Gait Disturbance; Gait Inability; Hypoaesthesia; Joint Swelling; Musculoskeletal Pain; Neck Pain; Peripheral Swelling; Pharyngeal Oedema; Rash; Therapeutic Product Effect Decreased	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773503	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202003004282			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773686	EXPEDITED (15-DAY)		DE, HO	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-245681		37 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Histoplasmosis Disseminated; Respiratory Failure	Hydroxychloroquine			S	Oral	Unk		Sun
	Methylprednisolone			S	Unknown	200 Milligram, Daily		Not Reported

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Prednisone			S		Unknown		40 Milligram, Daily		Mutual
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773712	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-024314		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Dia		Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported	
	Enoxaparin			S	Subcutaneous	80 Milligram		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram 1 Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773717	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595963		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	Intravenous drip	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773731	EXPEDITED (15-DAY)		DE	ES-AUROBINDO-AUR- APL-2020-024369		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram, Once A Day		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Not Reported	
	Tocilizumab			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773862	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595816			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

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Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773884	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596145		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous drip			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Acetaminophen			C				Not Reported
	Codeine			C				Not Reported
	Prednisone			C	Oral			Not Reported

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Prednisone			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17773971	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-246369		82 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Daily		Not Reported	
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported	
	Haloperidol			S	Oral	5 Gtt Drops, Daily		Not Reported	
	Haloperidol			S	Oral	5 Gtt Drops		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596655			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered; Deformity; Ill-Defined Disorder; Malaise; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope	Actemra			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Certolizumab Pegol			S	Subcutaneous			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Solution		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774166	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB-001325			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Nausea	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Ipca	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Ipca	
	Fluoxetine			C	Unknown	1 Dosage Form, Qd		Not Reported	
	Levothyroxine			C	Unknown	1 Dosage Form, Qd		Not Reported	
	Cerazette			C	Unknown	1 Dosage Form, Qd		Not Reported	
	Colecalciferol			C	Unknown	1 Dosage Form, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774196	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595905		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased;	Actemra			S	Unknown			Not Reported	
Diarrhoea; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	

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Failure	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596306		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Decreased;	Rituximab			S	Unknown			Not Reported
Contraindicated Product	Simponi			S	Subcutaneous			Not Reported
Administered; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Fibromyalgia;	Humira			S	Subcutaneous			Not Reported
Nasal Congestion;	Hydroxychloroquine			S	Unknown			Not Reported
Nasopharyngitis; Serum	Methotrexate			S	Unknown			Not Reported
Ferritin Decreased; Viral	Orencia			S	Unknown			Not Reported
Upper Respiratory Tract	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774396	EXPEDITED (15-DAY)		OT	PHHY2019DE192157			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conjunctivitis Bacterial;	Methotrexate			S	Unknown	Unk		Not Reported
Conjunctivitis Bacterial;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Novartis
Contusion; Cystitis;	Abatacept			S	Unknown	Unk		Not Reported
Diarrhoea; Fall; Myalgia;								
Respiratory Tract								
Infection; Respiratory								

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Tract Infection; Rhinitis;
Sinusitis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774409	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- GSH201709-005235			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Deformity; Drug Hypersensitivity; Drug Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Oral	400 Mg		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg		Concordia
	Methotrexate			S	Unknown	25 Mg, Weekly		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Arava			S	Oral	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Xeljanz			C		Unk		Not Reported
	Adalimumab			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774424	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020- 013591		45 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Doxiciclina			S	Oral			Not Reported	
	Doxiciclina			S				Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Azitromicina			S				Not Reported	
	Hidroxicloroquina			S	Oral			Not Reported	
	Hidroxicloroquina			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774466	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1233693		56 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypoacusis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774467	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233697		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported	
	Roactemra			S				Not Reported	
	Lopinavir/Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported	
Lopinavir/Ritonavir			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597691			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use In Unapproved Indication; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774847	EXPEDITED (15-DAY)		DS	CA-ROCHE-2595829		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Gold	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Actemra	C	Unknown	Not Reported
Arava	C	Oral	Not Reported
Bifidobacterium Bifidum	C		Not Reported
Celebrex	C	Unknown	Not Reported
Loperamide	C		Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported
Pantoprazole	C		Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C		Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17775254	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANSZ PHARMA-GSH201706-003681			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	

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Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Stomatitis; Terminal State; Thrombosis; Urticaria	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk	Concordia
	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine	S	Unknown	Unk	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	Unk	Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil	S	Unknown	400 Mg	Concordia
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Minocycline Hydrochloride	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Intra-arterial	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S			Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Anakinra	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Unknown	Unk	Not Reported

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Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	Unk Unk, Bid	Not Reported
Gold	S	Unknown	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	S	Subcutaneous	Unk	Not Reported
Ilaris	C			Not Reported
Methotrexate	C			Not Reported
Hydroxychloroquine Phosphate	C		Unk	Not Reported
Rituximab	C			Not Reported
Anakinra	C			Not Reported
Lyrica	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17775772	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593600		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported	
Arthropathy;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Contraindicated Product Administered; Drug Hypersensitivity; Drug									

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Ineffective; Dyspnoea; Gait Disturbance; Lupus- Like Syndrome; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Tuberculin Test Positive	Rituximab	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Celecoxib	S	Oral	Not Reported
	Celecoxib	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Toradol	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17776859	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1233507		27 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	250 Milligram Daily;		Not Reported
	Hidroxycloquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Nordimet 22,5 Mg Solucion Injectable En Pluma Precargada, 4 Plumas Pre Isdiben 20 Mg Capsulas Blandas , 50 Cápsulas			C	Subcutaneous	1 Iny Sc On Monday		Not Reported
				C	Oral	1 Cp Every 48 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17776951	EXPEDITED (15-DAY)		HO, LT	SI-ACCORD-181639		48 YR	Male	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Immune Thrombocytopenia;	Hydroxychloroquine			S	Oral	Strength: 200 Mg		Not Reported
Thrombocytopenia	Kaletra			S	Oral	(80mg+20mg)/MI Oral Solution, Dose 400mg/100		Not Reported

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					Mg				
	Piperacillin Sodium/Tazobactam		C						Not Reported
	Sodium		C						Not Reported
	Esmeron		C						Not Reported
	Metoclopramide		C						Not Reported
	Analgin		C						Not Reported
	Pantoprazole		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17777085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598364			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17777086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598053			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intestinal Perforation; Joint Swelling; Therapeutic Product Ineffective; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Adalimumab			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17777448	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA-GSH201902-000277			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Plavix			S	Unknown	Unk		Not Reported	
	Famotidine			S	Unknown	Unk		Not Reported	
	Venlafaxine Hydrochloride			S	Unknown	Unk		Not Reported	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Trandolapril			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Furosemide			S	Unknown	Unk		Not Reported	
	Nifedipine			S	Unknown	Unk		Not Reported	
	Loperamide			S	Unknown	Unk		Not Reported	
	Ambien			S	Unknown	Unk		Not Reported	
	Gabapentin			S	Unknown	Unk		Not Reported	
	Nexium			S	Unknown	Unk		Not Reported	

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Crestor	S	Unknown	Unk	Not Reported
Potassium Acetate	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	S	Unknown	Unk	Not Reported
Victoza	S	Unknown	Unk	Not Reported
Humira 40 Mg/0.8 MI	S	Subcutaneous	40 Mg, Qod	Not Reported
Humira 40 Mg/0.8 MI	S	Subcutaneous	40 Mg,Qow	Not Reported
Humira 40 Mg/0.8 MI	S			Not Reported
Flomax	S	Unknown	Unk	Not Reported
Reglan	S	Unknown	Unk	Not Reported
Trazodone	S	Unknown	Unk	Not Reported
Imdur	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17777683	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235485			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17777786	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235410		30 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Prednisone	S	Unknown	Actavis
	Cymbalta	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778059	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598054			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778115	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2083741		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Febrile Neutrophilic Dermatitis; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778149	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505935		61 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Ankle Arthroplasty; Arthralgia; Drug Ineffective; Hip Arthroplasty; Knee Arthroplasty; Pain In Extremity; Peripheral Swelling; Psoriasis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Gold (198 Au)			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778165	EXPEDITED (15-DAY)		OT	FR-APPCO PHARMA LLC-2083742		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Febrile Neutrophilic Dermatosis	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778290	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC- 2020185611		70 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Off Label Use; Pneumonia Escherichia; Product Use In Unapproved Indication; Ventricular Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778335	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593495		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Anti-Cyclic	Rituxan			S	Unknown			Not Reported
Citrullinated Peptide								
Antibody Positive;	Apo Hydroxyquine			S	Unknown			Not Reported
Arthropathy; Condition	Arava			S	Oral			Not Reported
Aggravated;								
Contraindicated Product	Cetirizine Hydrochloride			S	Unknown			Not Reported
Administered; Discomfort;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Drug Ineffective; Drug	Cetirizine			S	Unknown			Not Reported
Intolerance; Fatigue;	Hydrochloride;Pseudoephedrine							
Glossodynia; Hand	Hydrochloride							
Deformity; Hepatic	Cimzia			S	Subcutaneous			Not Reported
Enzyme Increased;								
Hypersensitivity; Infusion	Cortisone			S	Oral			Not Reported
Related Reaction; Joint								
Swelling; Maternal	Cortisone Acetate			S	Unknown			Not Reported
Exposure During	Desoximetasone			S	Unknown			Not Reported
Pregnancy; Pain;								
Pemphigus; Pericarditis;	Desoximetasone			S	Oral			Not Reported
Product Use Issue; Rash;								
Rheumatoid Factor	Diclofenac Sodium			S	Unknown			Not Reported
Positive; Swelling;	Enbrel			S	Subcutaneous			Not Reported
Synovitis; Systemic Lupus	Folic Acid			S	Unknown			Not Reported
Erythematous; Treatment	Folic Acid			S	Unknown			Not Reported
Failure; Wound	Folic Acid			S	Oral			Not Reported
	Fosamax			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydrocortisone Acetate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sarilumab	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Stelara	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Subcutaneous	Not Reported
Topicort [Desoximetasone]	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Acetaminophen	S	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported

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Salazopyrin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778359	EXPEDITED (15-DAY)		HO, OT	MX-APPCO PHARMA LLC-2083743		29 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nocardiosis	Hydroxychloroquine Sulfate			S	Oral			Appco Pharma	
	Prednisone			S	Oral			Not Reported	
	Mycophenolate Mofetil			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778367	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA- 2020SE60059		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Purpura; Thrombocytopenia	Inexium			S	Intravenous (not otherwise specified)			Astrazeneca	
	Cefotaxime Base			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycine Anhydrous			S	Oral			Not Reported	
	Noradrenaline			S	Intravenous (not otherwise specified)			Not Reported	
	Lovenox			S	Subcutaneous			Not Reported	
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Sufentanil			C				Not Reported	
	Nimbex			C				Not Reported	
	Hypnovel			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778446	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS- 2020M1046089			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Death; Intentional Product Misuse; Off Label Use	Azithromycin	S	Unk	Not Reported
	Plaquenil /00072603/	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778478	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235393			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Prednisone			S	Unknown			Actavis
Alopecia; Contraindicated	Methotrexate			S	Unknown			Barr
Product Administered;	Actemra			S	Unknown			Not Reported
Pain; Pemphigus;	Arava			S	Unknown			Not Reported
Rheumatoid Arthritis;	Cimzia Single-Use Pre- Filled Syringe			S	Subcutaneous			Not Reported
Systemic Lupus Erythematosus	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235252			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Methotrexate			S	Unknown			Barr

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Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Prednisone	S	Unknown	Actavis
	Alendronate Sodium	S	Unknown	Actavis
	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778602	EXPEDITED (15-DAY)		OT	DE-APPCO PHARMA LLC-2083745		21 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemophagocytic Lymphohistiocytosis; Withdrawal Syndrome	Hydroxychloroquine Sulfate			S	Unknown			Appco Pharma	
	Prednisolone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778628	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES- 1233508		45 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Azitromicina (7019a)			S				Not Reported	

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	Hidroxiclороquina (2143a)	S	Oral	400 Mg	Teva
	Hidroxiclороquina (2143a)	S			Teva
	Doxiciclina (1395a)	S	Oral	100 Mg	Not Reported
	Doxiciclina (1395a)	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778629	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233662		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxiclороquina (2143a)			S	Oral	400 Mg		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra Ceftriaxona (501a)			C C	Intravenous (not otherwise specified)	2 Gram		Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17779027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597533			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Parenteral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 486.0	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	C	Parenteral		Not Reported
Azathioprine	C	Unknown	1 Every 1 Days	Not Reported
Ciclosporin	C			Not Reported
Minocycline	C			Not Reported
Penicillamine	C			Not Reported
Phenylbutazone	C			Not Reported
Prednisolone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Tofacitinib	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17779230	EXPEDITED (15-DAY)	HO		CA-ROCHE-2593246		69 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Meningitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17779962	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020189648		48 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported	
	Enoxaparin			S	Subcutaneous	60 Mg, 2x/Day (Every 12 Hours)		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Total		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, 1x/Day For 6 Days		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	10 Mg, 1x/Day For 5 Days		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	5 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17780263	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235392		43 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Pain; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapy Partial Responder	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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	Rituximab	S	Intravenous drip					Not Reported
	Sulfasalazine	S	Unknown	2000 Milligram Daily;				Not Reported
	Sulfasalazine	S	Unknown	1000 Milligram Daily;				Not Reported
	Risedronate Sodium	C	Unknown					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17780732	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046150		85 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Bisoprolol			S		1.25 Mg, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S		200 Mg, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17780744	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046103			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Intentional Product Misuse; Loss Of Consciousness; Off Label Use; Product Use In Unapproved Indication; Ventricular Arrhythmia	Azithromycin			S		Unk		Not Reported	
	Plaquenil /00072603/			S		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17780745	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1046106			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Intentional Product Misuse; Off Label Use	Azithromycin			S		Unk		Not Reported	
	Plaquenil /00072602/			S		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17780884	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1046101			Unknown	FRA

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Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Azithromycin			S		Unk		Not Reported	
	Plaquenil /00072602/			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17780898	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1046072		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Olanzapine			S	Oral	7.5 Milligram, Qd		Not Reported	
	Plaquenil /00072603/			S	Oral	800 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17782760	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1045950		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported	
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan	
	Rocephine			S	Oral	2 Gram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17784090	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436771			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Neutropenia	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Imuran /00001501/			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Azathioprine

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	11271558	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1606866		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Increased; Condition Aggravated;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Hypertension; Joint Swelling; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased;	Humira			S	Unknown	40 Mg, Unk 3/C G2		Not Reported
Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Enbrel			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	12688972	EXPEDITED (15-DAY)		OT	CA-ROCHE-1675763			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Fissure; Arthralgia; Bronchitis; C-Reactive Protein Increased; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Intolerance; Dyspepsia; Fear; Joint Swelling; Joint Swelling; Laboratory Test Abnormal; Mucosal Inflammation; Pneumonia; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Abatacept			S	Unknown			Not Reported
	Cortisone			C	Oral			Not Reported
	Desoximetasone			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	12856089	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712817			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Discontinued Due To A Side Effect For 2 Years		Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous	Discontinued Due To Developing Cancer		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Taken For 2 Years,		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			Stopped Working	
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Minocycline	S	Unknown		Not Reported
Sulfasalazine	S	Unknown	Stopped Working Therapy Duration: 730 Days	Not Reported
Xeljanz	S	Oral		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Minocycline Hydrochloride	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Amoxicillin;Clavulanate Potassium	C			Not Reported
Amoxil [Amoxicillin]	C			Not Reported
Adalimumab	C			Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)		Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)		Not Reported
Bcg Vaccine	C	Unknown		Not Reported
Amoxicillin	C			Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown		Not Reported
Amoxil [Amoxicillin]	C	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amoxillat	C		Not Reported
Gold	C	Unknown	Not Reported
Hydroxychloroquine	C	Subcutaneous	Not Reported
Risedronate	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	13254993	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP006561		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Fentanyl			S	Unknown	Unk		Apotex
Arthralgia; Arthropathy;	Hydroxychloroquine			S	Unknown	Unk		Apotex
Blood Creatinine	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
Increased; Blood	Gabapentin			S	Oral	100 Mg, Bid		Apotex
Magnesium Increased;	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Once Every Four Weeks		Not Reported
Blood Potassium	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
Increased; Bone Cyst;	Celebrex			S	Oral	Unk		Not Reported
Crohn'S Disease;	Enbrel			S	Subcutaneous	50 Mg, Q.I.W		Not Reported
Deafness Neurosensory;	Enbrel			S	Subcutaneous	50 Mg, Bid		Not Reported
Deformity; Diarrhoea;	Methotrexate			S	Subcutaneous	Unk Unk, Q.Wk.		Not Reported
Drug Hypersensitivity;	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Once Every 4 Weeks		Not Reported
Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.		Not Reported
Intolerance; Dry Eye;	Orencia			S	Intravenous (not otherwise specified)	75 Mg, Once Every 4 Weeks		Not Reported
Epigastric Discomfort;	Orencia			S	Subcutaneous	Unk, Q.Wk.		Not Reported
Exostosis; Fatigue;	Oxycontin			S	Unknown	Unk		Not Reported
Gastrointestinal Disorder;	Sulfasalazine			S	Oral	2.5 G, Qd		Not Reported
Hypersensitivity; Infection;	Plaquenil /00072602/			S	Unknown			Not Reported
Joint Swelling; Mobility								
Decreased;								
Musculoskeletal Stiffness;								
Myocardial Infarction;								
Nausea; Osteoarthritis;								
Osteopenia;								
Osteosclerosis; Pain; Pain								
In Extremity; Pleural								
Fibrosis; Pleural								
Thickening; Presbycusis;								
Renal Impairment;								
Rheumatoid Arthritis; Skin								
Lesion; Sleep Disorder;								

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Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Treatment Failure	Myochrysin	S	Intramuscular	50 Mg, Unk	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Unk	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown		Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Gabapentin	C	Oral	100 Mg, Bid	Not Reported
	Genteal /00445101/	C	Unknown		Not Reported
	Lomotil /00034001/	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Unknown	2 Df, Bid	Not Reported
	Nexium /01479302/	C	Unknown	40 Mg, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Q.H.	Not Reported
	Omega 3 /01334101/	C	Unknown	1200 Mg, Bid	Not Reported
	Prednisone	C	Unknown	5 Mg, Qd	Not Reported
	Prednisone	C	Unknown	5 Mg, 1 Every 2 Hours	Not Reported
	Trazodone Hydrochloride	C	Oral	50 Mg, Q.H.	Not Reported
	Tylenol /00020001/	C	Oral	1000 Mg, Unk	Not Reported
	Vitamin D /00107901/	C	Unknown		Not Reported
	D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	40 Mg, Bid	Not Reported
	Acetaminophen	C	Oral	1000 Mg, Qd	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
	Omega-3 Fatty Acids	C	Unknown	Unk	Not Reported
	Risedronate Sodium	C	Unknown	36 Mg, Q.Wk.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	14535544	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0125		63 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Joint Arthroplasty; Mouth Ulceration; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Vasculitic Rash	Kineret			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	Dose: 12.5 Mg Once Daily		Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	Dose: 12.5 Mg 1x1 Daily		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous	12.5 Mg Daily		Not Reported
	Methotrexate			S	Oral	12.5 Milligram		Not Reported
	Methotrexate Sodium			S	Oral	Dose: 12.5 Mg		Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	15568769	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016-1700		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated	Methotrexate (Trade Name)			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Administered;	Unknown)				
Contusion; Drug	Methotrexate (Trade Name	S	Oral		Not Reported
Ineffective; Drug	Unknown)				
Intolerance; Fatigue;	Methotrexate (Trade Name	S	Oral		Not Reported
Product Use Issue	Unknown)				
	Methotrexate (Trade Name	S	Oral		Not Reported
	Unknown)				
	Methotrexate (Trade Name	S	Unknown		Not Reported
	Unknown)				
	Enbrel	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Apo-Hydroxyquine	S	Oral		Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	16499902	EXPEDITED (15-DAY)		OT	CA-SA-2019SA170806			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition	Arava			S	Oral	20 Mg		Sanofi
Aggravated; Drug	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
Ineffective; Fatigue; Joint	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
Swelling; Loss Of	Prednisone			S	Oral	5 Mg		Not Reported
Personal Independence In								
Daily Activities; Pain;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Peripheral Swelling	Sulfasalazine	S	Unknown	1000 G, Bid	Not Reported
	Actemra	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Unknown	20 Mg	Not Reported
	Orencia	S	Unknown	Unk Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	16645869	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202544			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S		200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	175 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	16651228	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202829			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S		400 Mg		Sanofi
	Methotrexate			S		20 Mg, Qd		Not Reported
	Leflunomide			S		20 Mg		Sanofi
	Enbrel			S				Not Reported
	Actemra			S		8 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S		750 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Meloxicam	C		Not Reported
Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	16945913	EXPEDITED (15-DAY)		OT	CA-ROCHE-2437307			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Chemicals;	Actemra			S	Subcutaneous			Not Reported
Arthralgia; Bone Density	Arava			S	Unknown			Not Reported
Decreased; C-Reactive	Leflunomide			S	Unknown			Not Reported
Protein Increased;	Meloxicam			S	Unknown			Not Reported
Crepitations; Deformity;	Methotrexate			S	Unknown			Not Reported
Diarrhoea; Dizziness;	Orencia			S	Unknown			Not Reported
Drug Ineffective; Drug	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Intolerance; Dry Eye;	Depo-Medrol			C	Unknown			Not Reported
Fatigue; Feeling	Diclofenac			C	Unknown			Not Reported
Abnormal; Fibromyalgia;	Humira			C	Unknown			Not Reported
Hand Deformity; Joint	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
Range Of Motion								
Decreased; Joint Swelling;								
Liver Disorder; Malaise;								
Muscular Weakness;								
Musculoskeletal Pain;								
Musculoskeletal Stiffness;								
Myalgia; Pain In Extremity;								
Peripheral Swelling;								
Pulmonary Toxicity; Rash								
Maculo-Papular; Rash								
Pruritic; Rheumatoid								
Arthritis; Rheumatoid								
Nodule; Synovial Cyst;								
Tenosynovitis; Upper								
Respiratory Tract Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	16969607	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191008623		40 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Adverse Drug Reaction; Adverse Event; Adverse Reaction; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Fatigue; Gastric Disorder; General Physical Health Deterioration; Insomnia; Joint Swelling; Malaise; Nausea; Off Label Use; Pain; Rash; Rheumatoid Arthritis; Sleep Disorder	Otezla			S	Oral			Celgene
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Unknown			Not Reported
	Minocin			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous			Not Reported
	Myochrysine			S	Parenteral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Unknown	250 Milligram		Not Reported
	Rituximab			S	Parenteral			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sirukumab			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Oral	10 Milligram		Not Reported
	Ustekinumab			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	10 Milligram		Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Stelara			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Methotrexate			C	Unknown	15 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	C	Unknown	15 Milligram	Not Reported
	Prednisone	C	Unknown	5 Milligram	Not Reported
	Rheumatrex	C	Unknown		Not Reported
	Rheumatrex	C	Unknown	15 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17019418	EXPEDITED (15-DAY)	HO		CA-ROCHE-2458073			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Intolerance; Intentional Product Use Issue; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17036319	EXPEDITED (15-DAY)	OT		CA-ROCHE-2462412			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Meloxicam			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Treatment Failure	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17221720	EXPEDITED (15-DAY)		HO	CA-ROCHE-2456725			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Human Antichimeric Antibody Positive; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gammagard			S	Intravenous (not otherwise specified)	Liquid Also Know As Immune Globulin (Human)		Not Reported
	Gammagard			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Oral	Not Reported
Triamcinolone	S	Other	Not Reported
Triamcinolone	S	Intra-articular	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17261070	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514041			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Solution For Injection		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17402847	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020058662		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Drug Withdrawal Syndrome; Hypoaesthesia; Pain; Paraesthesia	Lyrica			S		200 Mg		Pfizer
	Lyrica			S		"300 Mg Twice"		Pfizer
	Sildenafil Citrate			S		"20 Mg Three Times"		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		"200 Mg Twice"		Not Reported
	Trazodone			S		"100 Mg Once"		Not Reported
	Trazodone			S				Not Reported
	Atorvastatin			C		Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Klor-Con			C		Unk		Not Reported

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Detailed Report

Lexapro			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17420592	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0792		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthrodesis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Kineret			S	Unknown			Not Reported	
	Kineret			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Desoximetasone			C	Unknown			Not Reported	
	Desoximetasone			C	Unknown			Not Reported	
	Methotrexate			C	Oral			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17433728	EXPEDITED (15-DAY)		OT	DE-MACLEODS PHARMACEUTICALS US LTD-MAC2019025070			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia;	Sildenafil			S	Unknown	60 Milligram, Qd		Macleods	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Sildenafil	S	Unknown	30 Milligram, Qd, Film Coated Tablet	Macleods
	Omeprazole 20 Mg	S	Oral	40 Milligram, Qd, 1 Df. 20 Mg Bid	Not Reported
	Omeprazole 20 Mg	S	Oral	20 Milligram, Qd, 1 Df	Not Reported
	Ramipril	S	Oral	2.5 Milligram, Qd, 2 Df	Not Reported
	Ramipril	S	Unknown	5 Milligram, Qd	Not Reported
	Ramipril	S	Oral	1 Dosage Form, Bid	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid, 300 Mg Qd, 1 Df, Tid	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid, 300 Mg Qd, 1 Df, Tid	Not Reported
	Volibris	S	Oral	30 Milligram, Bid	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Volibris	S	Oral	30 Milligram, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Q.W. (Solution For Injection In Pre-Filled Syringe)	Not Reported
	Quensyl	S	Unknown	40 Milligram, Bid	Not Reported
	Quensyl	S	Unknown	1 Dosage Form, Bid (1-0-0), 20 Mg	Not Reported
	Eliquis	S	Unknown	5 Milligram, Qd, 2 Df Qd, 2.5 Mg Bid	Not Reported
	Eliquis	S	Unknown	1 Dosage Form, Bid	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Bid ((1-0-1))	Not Reported
	Spasmolyt	S	Unknown	30 Milligram, Qd (0 -0 -1)	Not Reported
	Spasmolyt	S	Unknown	1 Dosage Form, Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasmolyt	S	Unknown	15 Milligram, Qd	Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17557582	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200318930		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Dermatitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gallbladder Disorder; Groin Pain; Pancreatitis; Photosensitivity Reaction; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Citalopram			C				Not Reported
	Prednisolone			C				Not Reported
	Gold			C	Unknown			Not Reported
	Pantoloc /01263201/			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17605641	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200333272		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Laboratory Test Abnormal; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Simponi			S	Subcutaneous			Janssen	
	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous	Cimzia Single-Use Prefilled Syringe		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Asacol			S	Unknown			Not Reported	
	Azathioprine			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Budesonide	S			Not Reported
Entyvio	S	Intravenous (not otherwise specified)		Not Reported
Vedolizumab	S			Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Enbrel	C	Subcutaneous		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Tocilizumab	C	Endocervical		Not Reported
Valsartan	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Wellbutrin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17697006	EXPEDITED (15-DAY)		DE, OT	FR-ADVANSZ PHARMA-202004003543			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome; Off Label Use; Pneumonia Bacterial	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1000 Mg, Qd, (Film Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd, (Film Coated Tablet)		Concordia
	Ceftriaxone			C		Unk		Not Reported
	Enoxaparin			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Rifamycine [Rifamycin]			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Carbomere		C		Unk			Not Reported
		Metoclopramide		C		Unk			Not Reported
		Vitamin A [Retinol]		C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17721926	EXPEDITED (15-DAY)		OT	RU-ADVANSZ PHARMA-202004003973			Unknown	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Pressure Fluctuation; Diarrhoea; Dizziness; Off Label Use; Pneumonia; Pyrexia	Hydroxychloroquine			S	Oral	400 Mg, Bid		Concordia	
	Hydroxychloroquine			S	Oral	200 Mg, Bid (Maintaining Dose)		Concordia	
	Kaletra			S	Unknown	400 Mg, Bid (Q12h)		Not Reported	
	Azithromycin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17727115	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202004004354			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Off Label Use	Hydroxychloroquine			S	Unknown	400 Mg, Qd, Film-Coated Tablet		Concordia	
	Piperacillin			C		Unk		Not Reported	
	Amphotericine B			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17742406	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1229778		96 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Mg		Not Reported	
	Plaquenil			S	Unknown	400 Mg		Not Reported	
	Lasix 25 Mg Compresse			C				Not Reported	
	Novorapid			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Normix	C	Not Reported
Dobetin	C	Not Reported
Lantus	C	Not Reported
Movicol	C	Not Reported
Deltacortene 25 Mg Compresse	C	Not Reported
Pantorc 20 Mg Compresse	C	Not Reported
Gastroresistenti		
Cardirene 75 Mg	C	Not Reported
Metoprololo	C	Not Reported
	50 Mg	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17752357	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1044783		82 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Teicoplanin			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported	
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan	
	Haloperidol			S	Oral	5 Gtt Drops, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17752431	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010539		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Apo-Leflunomide			S	Unknown	Unk		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Certolizumab Pegol			S	Unknown	200 Mg, Q.O.Wk.		Not Reported	
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Q.O.Wk.		Not Reported	
	Certolizumab Pegol			S	Subcutaneous	200 Mg, Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methylprednisolone	S	Unknown	80 Mg, Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	400 Mg, Unk, 1 Every 8 Weeks	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	400 Mg, Unk	Not Reported
Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Rituxan	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17772419	EXPEDITED (15-DAY)		DE, OT	IT-INCYTE CORPORATION-2020IN004123			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cardiac Arrest; Multiple Organ Dysfunction Syndrome; Respiratory Failure; Sepsis	Inc424			S	Oral	5 Mg, Bid		Incyte
	Inc424			S				Incyte
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	1 Df, Bid		Not Reported
	Prezista			S	Unknown	800 Mg, Qd		Not Reported
	Clexane			S	Unknown	0.6 MI, Qd (6 Syringe)		Not Reported
	Rocefin			S	Intramuscular	2 G, Qd (1 Bottle)		Not Reported
	Plasil [Metoclopramide Hydrochloride]			C	Intravenous (not otherwise specified)	1 Df, Qd (Inet 5f 2 MI)		Not Reported
	Albumine Baxter			C	Intravenous (not otherwise specified)	50 G/MI, Qd (1 FI, 250 MI)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Antra [Omeprazole Magnesium]	C	Intravenous (not otherwise specified)	40 Mg, Qd (Infus, 1 Fl)	Not Reported
Noradrenalina [Norepinephrine Hydrochloride]	C	Intravenous (not otherwise specified)	4 MI/H (10 F)	Not Reported
Ringers Lactate	C	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Tazocin	C	Intravenous (not otherwise specified)	12 Fl (4g+0.500g), Qd	Not Reported
Oxepa	C	Intravenous (not otherwise specified)	40 MI/H	Not Reported
Fluimucil	C	Respiratory (inhalation)	1 Df, Qd (Aer, 10f)	Not Reported
Vici	C	Intramuscular	1 Df, Qd (5f)	Not Reported
Eutirox	C	Oral	1 Df, Qd (500cpr, 125 Mcg)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17778385	EXPEDITED (15-DAY)		OT	RO-AUROBINDO-AUR-APL-2020-024106			Male	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Pneumonia; Sars-Cov-2 Test Positive	Azithromycin			S	Unknown	Unk		Aurobindo
	Kaletra			S	Oral	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17778542	EXPEDITED (15-DAY)		HO, LT, OT	FR-CELLTRION INC.-2020FR022184			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Coronavirus Infection; Cough; Headache; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use;	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	Four Infusions (375 Mg/M2) Were Weekly		Not Reported
	Rituximab (Unknown)			S		Maintenance Therapy; 500 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pyrexia; Respiratory Failure; Therapeutic Response Unexpected	Prednisone	S	Unknown	15 Mg Daily	Not Reported
	Hydroxychloroquine Sulfate	S		200 Mg/8 Hour For 10 Days From Day #19	Not Reported
	Nebivolol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17778681	EXPEDITED (15-DAY)		HO	CA-ROCHE-2596430		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 2.0 Months		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 2.0 Months		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 2.0 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Viread			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17778789	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-		58 YR	Male	ESP

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2020RR-247120

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Metamizol (111a)			S	Intravenous (not otherwise specified)	2 Gram, Every 6 Hours		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17778804	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247111		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779033	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2597012		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral	4.0 Dosage Forms	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779152	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832233		54 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Pulmonary Oedema; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	Intravenous drip	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Actemra	C	Unknown	Not Reported
Sodium Aurothiomalate	C		Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779175	EXPEDITED (15-DAY)	HO		CA-ROCHE-2595777		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Rituximab			S	Intravenous drip			Not Reported	
Adverse Event;	Apo-Leflunomide			S	Oral			Not Reported	
Arthrodesis;	Cefazolin			S	Unknown			Not Reported	
Contraindicated Product	Certolizumab Pegol			S	Subcutaneous			Not Reported	
Administered; Drug	Certolizumab Pegol			S	Subcutaneous			Not Reported	
Hypersensitivity; Drug	Certolizumab Pegol			S	Subcutaneous			Not Reported	
Ineffective; Hand	Certolizumab Pegol			S	Subcutaneous			Not Reported	
Deformity; Hospitalisation;	Cimzia			S	Subcutaneous			Not Reported	
Infection; Limb Operation;	Enbrel			S	Unknown			Not Reported	
Rash; Rheumatoid	Humira			S	Subcutaneous			Not Reported	
Arthritis; Shoulder	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Arthroplasty; Urticaria	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	

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Sulfate]
Remicade

S

Intravenous (not
otherwise specified)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779238	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247037		78 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun
	Plaquenil			S	Oral	600 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779329	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-037950		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Intentional Product Use Issue	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779338	EXPEDITED (15-DAY)		DE	CA-ROCHE-2597863			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Deep Vein Thrombosis;	Actemra			S	Unknown			Not Reported
Diverticulitis; Drug	Actemra			S	Unknown			Not Reported
Ineffective; Joint Swelling; Off Label Use; Pain;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Pulmonary Embolism;	Rituximab			S				Not Reported
Renal Failure	Rituximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Methotrexate	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Ilaris	S	Subcutaneous	Not Reported
Ilaris	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17779347	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2020079500		30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
III-Defined Disorder	Benlysta Solution For Infusion			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported

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Cellcept			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-May-2020	17779405	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005272			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Corneal Degeneration	Hydroxychloroquine			S		Unk		Concordia		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-May-2020	17779489	EXPEDITED (15-DAY)		OT	NL-ADVANZ PHARMA-202004005018			Unknown	NLD	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Effective For Unapproved Indication; Off Label Use; Superinfection Bacterial	Hydroxychloroquine			S	Unknown	200 Mg, Tid, Film-Coated Tablet		Concordia		
	Hydroxychloroquine			S				Concordia		
	Azithromycine			C		Unk		Not Reported		
	Zinc Orotate			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-May-2020	17780060	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245719		77 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligrams, Daily		Sun		
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Daily		Not Reported		
	Clexane			S				Not Reported		
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-May-2020	17780114	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597489		62 YR	Female	CAN	

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Weight Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780165	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1233663		57 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780193	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1233665		53 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported

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14-May-2020	17780194	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233691		27 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	800mg Day (Load) Followed 400 Mg Day		Teva	
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva	
	Ivermectina (7778a)			S	Oral	12 Mg Du		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780279	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247122		47 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Paracetamol			S	Oral	1 Gram, Tid		Ohm Lab	
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780317	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598582		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Drug Ineffective; Drug	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	

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Intolerance; Dyspepsia;	Actemra	S	Unknown	Not Reported
Food Intolerance; Hepatic	Azathioprine	S	Unknown	Not Reported
Enzyme Increased;	Azathioprine	S	Unknown	Not Reported
Hypertension; Injection	Enbrel	S	Subcutaneous	Not Reported
Site Inflammation; Off	Humira	S	Subcutaneous	Not Reported
Label Use; Pneumonia;	Hydroxychloroquine	S	Unknown	Not Reported
Pruritus; Rheumatoid	Leflunomide	S	Unknown	Not Reported
Arthritis; Urosepsis	Methotrexate	S	Unknown	Not Reported
	Methyl Salicylate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780345	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235248			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Contraindicated	Methotrexate			S	Unknown			Barr	
Product Administered;	Prednisone			S	Unknown			Actavis	
Drug Ineffective;	Actemra			S	Unknown			Not Reported	
Fibromyalgia; Hernia;	Arava			S	Unknown			Not Reported	
Hypertension;	Humira			S	Unknown			Not Reported	
Hypoglycaemia;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Lymphoma; Thyroid	Orencia			S	Unknown			Not Reported	
Disorder	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	

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14-May-2020	17780437	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594910		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Fluctuation; Blood Pressure Increased;	Amlodipine Besilate			S	Oral			Not Reported
Colitis; Dental Caries;	Amlodipine Besilate			S	Unknown			Not Reported
Diabetes Mellitus	Amlodipine Besilate			S	Oral			Not Reported
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Asacol			S	Unknown			Not Reported
Gastrointestinal Disorder;	Diamicron			S	Unknown			Not Reported
Haematochezia;	Enbrel			S	Subcutaneous			Not Reported
Hypertension;	Gliclazide			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Humira			S	Subcutaneous			Not Reported
Pain In Extremity;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Peripheral Swelling;	Leflunomide			S	Unknown			Not Reported
Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous			Not Reported
Vitamin D Deficiency;	Orencia			S	Unknown			Not Reported
Weight Increased	Rituxan			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Diphenhydramine			C				Not Reported
	Ebastine			C				Not Reported
	Ferrous Gluconate			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin D3			C				Not Reported
	Acetaminophen			C				Not Reported
	Atacand Plus			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780482	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235418		67 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anorectal Discomfort; Arthralgia; Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Dyspepsia; Gait Inability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Skin Hyperpigmentation; Treatment Failure	Prednisone			S	Unknown			Actavis	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported	
	Fentanyl			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780489	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865689		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fatigue; Hypersensitivity; Insomnia; Iodine Allergy; Off Label Use; Pain; Product Use In Unapproved Indication; Product Use Issue; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 4.0 Year(S)		Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 3.0 Months		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Venlafaxine Hydrochloride			S	Oral	Every 1 Day(S)		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Hydrodiuril			C	Unknown			Not Reported	
	M-Eslon			C	Unknown	Capsule, Extended		Not Reported	

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Statex [Morphine Sulfate]			C	Unknown		Release		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780500	EXPEDITED (15-DAY)	OT		CA-ROCHE-2596647			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Rituximab			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Acetaminophen			C	Oral			Not Reported	
	Diphenhydramine			C	Oral			Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Methylprednisolone			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780536	EXPEDITED (15-DAY)	OT		CA-ROCHE-2597205			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	

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Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780665	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597998			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

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Sulfasalazine			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17781433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593776			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Tofacitinib Citrate			S	Unknown			Not Reported	
	Leflunomide			C				Not Reported	
	Sulfasalazine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17782195	DIRECT	Y	OT			73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication; Therapy Interrupted	Hydroxychloroquine			S	Oral			Sandoz	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17782822	DIRECT	Y	DE			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Clinical Trial Participant;	Hydroxychloroquine			S	Oral		9 DAY	Sandoz	

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Product Use In
Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17782864	DIRECT	Y	DE			72 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		0.93 DAY	Sandoz	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17782994	EXPEDITED (15-DAY)		OT	NVSC2020US128816			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Mycophenolate Mofetil			S	Transplacental	Unk		Novartis	
	Prednisone			S	Transplacental	Unk		Not Reported	
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported	
	Azathioprine			S	Transplacental	Unk		Not Reported	
	Tacrolimus			S	Transplacental	Unk		Not Reported	
	Lovenox			S	Transplacental	Unk		Not Reported	
	Bactrim			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17782995	EXPEDITED (15-DAY)		HO, LT, OT	JP-ALVOGEN-2020- ALVOGEN-108377		41 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Disorder; Blood Pressure Increased; Caesarean Section; Hormone Level Abnormal; Hypogonadism; Infarction;	Estradiol			S	Transdermal			Not Reported	
	Tacrolimus			S				Not Reported	
	Progesterone			S	Vaginal			Not Reported	
	Dydrogesterone			S	Oral			Not Reported	

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Maternal Exposure During Pregnancy; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Uterine Atony; Vaginal Haemorrhage	Prednisolone Hydroxychloroquine	S S							Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17782998	DIRECT	Y	OT			45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		5 DAY	Sandoz

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17783422	NON-EXPEDITED			US-PFIZER INC-2020192270		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Sulfasalazine Hydroxychloroquine			S S				Pfizer Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17783531	NON-EXPEDITED			US-PFIZER INC-2020192170		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance	Methotrexate Sodium			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Azathioprine			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17783975	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1234425		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gamma-Glutamyltransferase Increased; Transaminases Increased	Azithromycine Anhydre			S	Oral			Not Reported	
	Augmentin			S	Oral	3g		Not Reported	
	Plaquenil			S	Oral	200 Mg X 3 Per Day		Not Reported	
	Lovenox			S	Subcutaneous			Not Reported	
	Acupan			C				Not Reported	
	Lamictal			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784010	DIRECT	Y	OT			85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		6.42 DAY	Sandoz	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784015	DIRECT	Y	DE			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Clinical Trial Participant; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		1.02 DAY	Sandoz	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784019	DIRECT	Y	OT			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine	S	Oral	8.03 DAY	Sandoz

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784026	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA- 202004003912			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			C	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Dopamine			C		Low Dose		Not Reported
	Cardura			C	Oral	8 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784110	EXPEDITED (15-DAY)		DE, OT	US-ADVANSZ PHARMA- 202005005124			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death; Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Concordia

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17784210	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1234252		72 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784713	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005093			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis	Hydroxychloroquine			S		Unk		Concordia	
	Xeljanz Xr			S	Oral	11 Mg, Qd		Not Reported	
	Methotrexate			S		Unk		Not Reported	
	Prednisone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784740	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234253		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784959	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020191445		45 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Azithromycin			S				Pfizer	
	Doxycycline Hyclate			S	Oral	100 Mg, 2x/Day (100 Mg Every 12 Hours)		Pfizer	
	Doxycycline Hyclate			S				Pfizer	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day (400 Mg Day)		Not Reported	
	Hydroxychloroquine			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785260	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234538		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785273	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234539		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Sulpirida (3076a)			S	Oral	150 Milligram Daily;		Not Reported	
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785276	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234791		45 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785357	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020187763		39 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Long Qt Syndrome; Off Label Use; Product Use In Unapproved Indication; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 2x/Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Metoclopramid [Metoclopramide]			S	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, 4x/Day		Not Reported
	Cefotaxim			C	Intravenous drip	4 G, 2x/Day		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, 1x/Day		Not Reported
	Midazolam			C	Intravenous drip	100 Mg, 1x/Day		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	20 Ug, 4x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785416	EXPEDITED (15-DAY)		DE, HO	MX-ADVANSZ PHARMA-202004005048			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatine Increased; Off Label Use; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		1 Dosage Form, Bid		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Ceftriaxone			C				Not Reported
	Azithromycin			C				Not Reported
	Methylprednisolone			C				Not Reported
	Enoxaparin			C				Not Reported
	Lopinavir+ Ritonavir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785463	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202004003974			Unknown	USA

FDA Adverse Event Reporting System

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Disorder	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785480	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1234785		48 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Colchicina (142a)			S	Oral	1 Milligram Daily;		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785486	DIRECT	Y	OT			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		9.81 DAY	Sandoz	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234786		71 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785505	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234790		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785508	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1048030		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cornea Verticillata	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Not Reported	
	Hydroxychloroquine			S	Unknown	1200 Milligram, Qd, 21.9 Mg/Kg/Day		Not Reported	
	Everolimus			C	Unknown	10 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785570	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233969			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In	Prednisone			S	Oral			Actavis	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Daily Activities; Pain; Peripheral Swelling	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	2000 Gram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785573	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233979			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	17785593	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234261		43 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosis	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Topicort	S	Oral		Not Reported
	Topicort	S	Cutaneous		Not Reported
	Leflunomide	C			Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785597	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234474			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety Disorder;	Prednisone			S	Unknown			Actavis	
Confusional State; Hepatic Steatosis; Infection;	Methotrexate			S	Unknown			Barr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Memory Impairment;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Nausea; Nightmare; Pain;	Humira	S	Subcutaneous	Not Reported
Polymyalgia Rheumatica;	Acetaminophen	C		Not Reported
Rheumatoid Arthritis;	Macrobid [Calrithromycin]	C		Not Reported
Visual Impairment				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17786218	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020189472		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported
	Kaletra			S	Oral	2 Df, 2x/Day		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Dolquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17786244	EXPEDITED (15-DAY)		HO	CA-ROCHE-2595760			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Therapy Duration: 2.0 Months		Not Reported

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Orencia	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Months Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17786577	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1234629		66 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Purpura; Thrombocytopenia	Azithromycine Anhydre			S	Oral			Not Reported
	Cefotaxime Base			S	Intravenous (not otherwise specified)			Not Reported
	Inexium			S	Intravenous (not otherwise specified)			Not Reported
	Noradrenaline			S	Intravenous (not otherwise specified)			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Sufentanil			C				Not Reported
	Nimbex			C				Not Reported
	Hypnovel			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17786842	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202004004609			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective For	Hydroxychloroquine			S				Concordia
	Azithromycin			S		Unk		Not Reported

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Unapproved Indication		Actemra		S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17786865	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1046344		96 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S		500 Milligram, Qd		Not Reported	
	Plaquenil /00072603/			S		400 Milligram, Qd		Mylan	
	Lasix /00032601/			C		25 Milligram, Qd		Mylan	
	Novorapid			C				Mylan	
	Normix			C				Mylan	
	Lantus			C				Mylan	
	Movicol /01749801/			C				Mylan	
	Deltacortene			C				Mylan	
	Pantorc			C				Mylan	
	Cardirene			C				Mylan	
	Metoprololo			C		50 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787004	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020189427		64 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholangiolitis; Hypertransaminasaemia; Off Label Use	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported	
	Urbason Solub			C	Intravenous (not otherwise specified)	40 Mg		Not Reported	
	Antra [Omeprazole]			C		Unk		Not Reported	
	Clexane			C	Subcutaneous	4000 Kiu		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787014	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235520		83 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hyponatraemia	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Mg Day		Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported	
	Symbicort Turbuhaler 160 Microgramos/4,5			S	Respiratory (inhalation)	6 Dosage Forms Daily; 2- 2-2		Not Reported	
	Microgramos/Inhalacion Polvo Salbutamol			S	Respiratory (inhalation)	6 Dosage Forms Daily; 2- 2-2 Inh		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787015	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1234918			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nephrotic Syndrome	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Barr	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Prednisone			S	Oral			Actavis	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787017	EXPEDITED (15-DAY)		HO, OT	CA-CELGENEUS-CAN- 20200503123			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaphylactic Shock; Diarrhoea; Drug Ineffective; Drug Intolerance; Hypersensitivity; Nausea; Renal Impairment;	Otezla			S	Oral			Celgene	
	Cosentyx			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram		Not Reported	
	Infliximab			S	Intravenous (not	520 Milligram		Not Reported	



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otherwise specified)

S

20 Milligram

S

Unknown

20 Milligram

Not Reported

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood	Otezla			S	Unknown	120 Milligram		Celgene
Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein	Otezla			S				Celgene
Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Otezla			S				Celgene
	Rituximab			S	Intravenous drip	2000 Milligram		Not Reported
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	25 Milligram		Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral	600 Milligram		Not Reported
	Ibuprofen			S	Oral			Not Reported
	Infliximab			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported

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Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	15 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	70 Milligram	Not Reported
Methotrexate	S	Unknown	10 Milligram	Not Reported
Remicade	S	Intravenous drip		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Benadryl	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Prednisone	C	Unknown		Not Reported
Uloric	C	Unknown	160 Milligram	Not Reported
Xeljanz	C	Unknown		Not Reported
Oxycodone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787599	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234249			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Demyelination; Dermatomyositis; Drug Ineffective; Drug Intolerance; Fatigue; Mental Disorder; Muscle Injury; Myalgia; Off Label Use; Product Use In Unapproved Indication; Pruritus; Rash	Mycophenolate Mofetil Methotrexate Prednisone Hydroxychloroquine Sulfate	S S S S	Unknown Unknown Unknown Unknown	3 Milligram Daily;	Teva Barr Actavis Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787750	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234894		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Arthralgia; Arthropathy; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Humira			S	Unknown	20 Milligram Daily;		Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Actemra			S	Unknown			Not Reported
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235258		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug	Methotrexate			S	Subcutaneous			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Actavis

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Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling; Rheumatoid Arthritis	Sulfasalazine	S	Unknown	2000 Milligram Daily;	Not Reported
	Orencia	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram Daily;	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown	20 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787913	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1233963		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Erythema; Gastric Haemorrhage; Nephrolithiasis; Peripheral Swelling; Pneumonia; Pulmonary Fibrosis; Skin Haemorrhage; Skin Warm	Prednisone			S	Unknown	5 Milligram Daily;		Actavis
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Arava			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported
	Levofloxacin			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Fentanyl			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17788063	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1046493		78 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Electrocardiogram Qt	Azithromycin	S	Oral	500 Milligram, Qd	Not Reported
Prolonged; Off Label Use	Plaquenil /00072602/	S	Oral	600 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17788562	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1046609		47 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Paracetamol			S	Oral	1gr Cada 8h		Not Reported
	Dexketoprofeno /01363801/			S	Intravenous (not otherwise specified)	25 Mg Cada 8 Horas		Mylan
	Hidroxiclороquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxiclороquina /00072601/			S				Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Tocilizumab			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17788601	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046601		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan
	Hidroxiclороquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxiclороquina /00072601/			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17788615	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046603		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Milligram, Qd (500 Mg Dia)	Not Reported
	Azithromycin	S			Not Reported
	Metamizol /06276701/	S	Intravenous (not otherwise specified)	2 Gram, Q6h (2gr Cada 6 Horas)	Mylan
	Hidroxicloroquina /00072601/	S	Oral	400 Milligram, Qd (400 Mg Dia)	Mylan
	Paracetamol	S	Intravenous (not otherwise specified)	1 Gram, Q8h (1gr Cada 8 Horas)	Mylan
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram, Total	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17790362	EXPEDITED (15-DAY)		OT	CA-009507513-2005CAN004538		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Cerebrovascular Accident; Diverticular Perforation; Drug Hypersensitivity; Drug Intolerance; Insomnia; Joint Swelling; Knee Arthroplasty; Pain; Peripheral Swelling; Psoriasis; Psoriatic Arthropathy; Rash; Skin Reaction; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Fosamax			S	Unknown			Merck
	Actemra			S	Unknown			Not Reported
	Aspirin			S	Unknown			Not Reported
	Calcium (Unspecified)			S	Unknown			Not Reported
	Fosinopril Sodium			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Formulation: Solution Subcutaneous		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Morphine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Tylenol			S	Unknown	Unk		Not Reported
	Vitamin D (Unspecified)			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17790410	DIRECT	Y	OT			78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S	Oral		5.95 DAY	Sandoz	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17791142	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-181309			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Torsade De Pointes	Hydroxychloroquine			S		Twice On Day 1, Then 400 Mg Daily On Days 2 Through 5		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	12441101	EXPEDITED (15-DAY)		OT	CA-ROCHE-1768215		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Arthralgia; Chronic Sinusitis; Diarrhoea; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Off Label Use; Osteoporosis; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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Hydroxychloroquine	S	Unknown	Not Reported
Inflectra [Infliximab]	S	Intravenous (not otherwise specified)	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	12715328	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1825208		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	6 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Dorzolamide Hydrochloride/Timolol Maleate			S	Ophthalmic			Not Reported
	Levothyroxine			S	Unknown			Not Reported

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Prednisone	S	Unknown	Not Reported
Tylenol No.2	S	Unknown	Not Reported
Ramipril	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Codeine Phosphate	S	Unknown	Not Reported
Cosopt	C	Unknown	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	As Required
Diphenhydramine	C	Oral	Not Reported
Hydroxychloroquine Phosphate	C	Oral	Not Reported
Meprobamate	C		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Tylenol	C		Not Reported
Phosphoric Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	12890986	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP013207		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hospitalisation; Hypersensitivity; Infection;	Apo-Gabapentin			S	Oral	100 Mg, Bid		Apotex
	Apo-Fentanyl Matrix			S	Unknown	Unk		Aveva
	Celecoxib			S	Oral	Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Sulfasalazin			S	Oral	2.5 G, Qd		Not Reported
	Sulfasalazin			S	Oral	500 Mg, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	488 Mg, Q.M.T.		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported

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Nausea; Osteoarthritis; Osteopenia; Pleural Fibrosis; Pleural	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Thickening; Presbycusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate Sodium	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Unk, Q.Wk.	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Q.3w	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
	Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Q.M.T., 1 Every 1 Month	Not Reported
	Arava	S	Oral	20 Mg, Qd, 1 Every 1 Day	Not Reported
	Acetaminophen W/Oxycodone Hydrochloride	C	Unknown	1 Df, Prn	Not Reported
	Oxycodone Terephthalate	C	Unknown	Unk, 1.0 Dosage, As Required	Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	750 Mg, Q.M.T.	Not Reported
	Actonel	C	Unknown	36 Mg, Q.Wk.	Not Reported
	Calcium	C	Unknown	Unk	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	1 Df, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	2.5 Mg, Qd	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Qd	Not Reported
	Ergocalciferol	C	Unknown	400 Iu, Q.Wk.	Not Reported
	Esomeprazole Magnesium	C	Unknown	40 Mg, Bid	Not Reported
	Esomeprazole Magnesium	C	Unknown	400 Iu, Qd	Not Reported
	Ferrous Gluconate	C	Unknown	300 Mg, Qd	Not Reported
	Loperamide Hydrochloride	C	Unknown	2.5 Mg, Unk	Not Reported
	Nasonex	C	Nasal	2 Df, Bid	Not Reported
	Nasonex	C	Unknown	Unk, Bid	Not Reported
	Nortriptyline Hydrochloride	C	Oral	10 Mg, Unk	Not Reported

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Perphenazine	C	Oral	10 Mg, Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Mg, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Mg, Qd	Not Reported
Tylenol /00020001/	C	Oral	1000 Mg, Qd	Not Reported
Vitamin D /00107901/	C	Unknown	400 Unk, Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid W/Eicosapentae/06850301/	C	Unknown	1200 Mg, Bid, 2 Every 1 Day	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Mg, Bid	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Vitamin C /00008001/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	13028484	NON-EXPEDITED			US-PFIZER INC- 2016577872		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort;	Xeljanz Xr	S	11 Mg, 1x/Day	Pfizer
Body Height Decreased;	Hydroxychloroquine	S	200 Mg, Daily	Not Reported
Diarrhoea; Dyspepsia;	Hydroxychloroquine	S	200 Mg, 2x/Day	Not Reported
Eructation; Flatulence;	Pravastatin	C	20 Mg, 1x/Day	Not Reported
Gastroesophageal Reflux Disease; Malaise;	Lisinopril	C	10 Mg, 1x/Day	Not Reported
Nervousness; Vomiting	B6	C	100 Mg, Unk	Not Reported
	B6	C	100 Mg, Unk	Not Reported
	D3	C	1000 Iu, Unk	Not Reported
	Omeprazole	C	20 Mg, 1x/Day (In Morning)	Not Reported
	Docusate Sodium	C	100 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	13119773	EXPEDITED (15-DAY)		OT	CA-ROCHE-1880386		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	S	Oral	Not Reported
	Naprosyn [Naproxen]	C	Unknown	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	13210436	EXPEDITED (15-DAY)		OT	US-SA-2016SA235895		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Arava			S	Oral	20 Mg,Qd		Sanofi
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg,Qd		Sanofi
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Oral	5 Mg,Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg,Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg,Qw		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	5 Mg,Qd		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Unknown	Unk Unk,Unk		Not Reported
	Infliximab			S	Unknown	300 Mg,Qd		Not Reported
	Pantoprazole			C	Unknown	Unk Unk,Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Atorvastatin			C	Unknown	Unk Unk,Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	13271290	EXPEDITED (15-DAY)		DS	CA-ROCHE-1898441		54 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ankle Operation;	Actemra	S	Unknown	Not Reported
Arthralgia; Arthropathy;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Asthenia; C-Reactive Protein Increased;	Arava	S	Unknown	Not Reported
Cataract; Constipation;	Celecoxib	S	Unknown	Not Reported
Contraindicated Product Administered; Drug Ineffective; Fatigue;	Celecoxib	S	Unknown	Not Reported
Hepatic Cirrhosis; Herpes Zoster; Knee Arthroplasty;	Enbrel	S	Unknown	Not Reported
Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Celebrex	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	13704410	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1955888			Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Actemra			S	Unknown			Not Reported
Arthropathy; C-Reactive	Actemra			S				Not Reported
Protein Abnormal; C-	Rituxan			S	Intravenous (not			Not Reported
Reactive Protein					otherwise specified)			
Increased;	Rituxan			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Deep Vein	Rituxan			S	Unknown			Not Reported
Thrombosis; Diverticulitis;	Anakinra			S	Unknown			Not Reported
Drug Hypersensitivity;	Anakinra			S				Not Reported
Drug Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Feeling	Enbrel			S				Not Reported
Abnormal; Haemoglobin	Humira			S	Subcutaneous			Not Reported
Decreased; Herpes	Humira			S	Unknown			Not Reported
Zoster; Intentional Product	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Use Issue; Interstitial Lung	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Disease; Joint Swelling;	Ilaris			S	Intravenous (not			Not Reported
Myocardial Infarction; Off					otherwise specified)			
Label Use; Pain;	Ilaris			S	Subcutaneous			Not Reported
Photosensitivity Reaction;								Not Reported
Pulmonary Embolism;								Not Reported
Pulmonary Thrombosis;								Not Reported
Red Blood Cell								Not Reported
Sedimentation Rate								Not Reported
Increased; Renal Failure;								Not Reported
Sepsis; Stomatitis;								Not Reported
Terminal State;								Not Reported
Thrombosis; Urticaria								Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Marijuana	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sodium Aurothiomalate	S		Not Reported
Rituxan	S	Unknown	Not Reported
Rituxan	S		Not Reported
Xeljanz	S	Oral	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Urelumab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	13932807	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017292		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Tenderness;	Hydroxychloroquine			S	Unknown	Unk		Apotex
Adverse Drug Reaction;	Apo-Leflunomide			S	Unknown	Unk		Apotex
Arthralgia; Arthropathy;	Actemra			S	Intravenous (not	Unk		Not Reported
Drug Ineffective; Fatigue;					otherwise specified)			
Groin Pain; Joint Injury;								

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Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling;	Enbrel	S	Unknown	Unk	Not Reported
Musculoskeletal Stiffness; Pain; Pain In Extremity; Peripheral Swelling;	Humira	S	Subcutaneous	Unk	Not Reported
Retinal Toxicity;	Methotrexate Sodium	S	Unknown	Unk	Not Reported
Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Arava	S	Unknown	Unk	Not Reported
	Tramadol Hydrochloride	C	Oral	50 Mg, Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Xeljanz	C	Oral	50 Mg, Bid	Not Reported
	Rabeprazole Sodium	C	Unknown	20 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	14169090	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210728			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Leflunomide			S	Oral	20 Mg,Unk		Sanofi
	Sodium Aurothiomalate			S	Parenteral	50 Mg,Unk		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Unk		Sanofi
	Leflunomide			S		20 Mg		Sanofi
	Methotrexate			S	Unknown	20 Mg,Qd		Not Reported
	Actemra			S	Unknown	8 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	750 Mg,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	14249112	EXPEDITED (15-DAY)		DS, OT	CA-SA-2017SA232046			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Hydroxychloroquine			S	Oral	200 Mg,Bid		Sanofi
	Arava			S	Oral	20 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg,Qw		Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	1 Df, Qd		Not Reported
	Sulfasalazine			S	Unknown	1000 Mg,Bid		Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported
	Humira			S	Subcutaneous	Unk Unk, Qd		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			C	Oral	5 Mg,Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	15622519	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557164-00		59 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Tremor	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not			Not Reported

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			otherwise specified)	
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Adalimumab	S	Unknown		Not Reported
Adalimumab	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Pantoprazole Magnesium	C		Enteric Coated	Not Reported
Tenofovir Disoproxil Fumarate	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported
Zopiclone	C			Not Reported
Pantoprazole Sodium Anhydrous	C			Not Reported
Pantoprazole	C	Unknown		Not Reported
Pantoprazole Bluefish	C			Not Reported
Tenofovir Disoproxil	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	15631632	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2018-CA-978035		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diffuse Large B-Cell Lymphoma	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S				Not Reported
	Methotrexate Sodium			S	Unknown			Barr
	Methotrexate Sodium			S				Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr

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Mycophenolate Mofetil	S	Unknown	Teva
Mycophenolate Mofetil	S		Teva
Prednisone	S	Unknown	Actavis
Prednisone Acetate	S	Unknown 15 Milligram Daily;	Actavis
Prednisone Acetate	S		Actavis
Hydroxychloroquine	S	Unknown 200 Milligram Daily;	Not Reported
Hydroxychloroquine	S		Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	15705980	EXPEDITED (15-DAY)		OT	CA-009507513-1812CAN000060			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Fosamax			S	Unknown	Unk		Merck
Abdominal Pain Upper;	Vasotec			S	Unknown	Unk		Merck
Arthralgia; Cardiac Failure;	Vasotec			S	Unknown	Unk		Merck
Cardiac Failure	Cozaar			S	Unknown	Unk		Merck
Congestive;	Cozaar			S	Unknown	Unk		Merck
Contraindicated Product	Cozaar			S	Unknown	Unk		Merck
Administered; Cough;	Arava			S	Unknown	Unk		Not Reported
Diarrhoea; Drug	Biaxin			S	Unknown	Unk		Not Reported
Hypersensitivity; Drug	Celebrex			S	Unknown	Unk		Not Reported
Ineffective; Drug	Ciprofloxacin			S	Unknown	Unk		Not Reported
Intolerance; Dyspnoea;	Ciprofloxacin			S	Unknown	Unk		Not Reported
Gastric Disorder;	Clindamycin			S	Unknown	Unk, Unknown		Not Reported
Headache; Hepatic	Codeine			S	Unknown	Unk		Not Reported
Steatosis; Hypertension;	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
Loss Of Employment;	Enbrel			S	Subcutaneous	50 Milligram, 1 Every 1 Week		Not Reported
Malaise; Nausea; Off								
Label Use; Product Use								
Issue; Rash; Therapeutic								
Product Effect Decreased								

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Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Hydralazine Hydrochloride	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, 1 Every 1 Week	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S		Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Pantoprazole Magnesium	S	Unknown	Unk	Not Reported
Pariet	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Penicillin G	S	Unknown	Unk	Not Reported
Keflex	S	Unknown	Unk, Unknown	Not Reported
Penicillin (Unspecified)	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Cephalexin	S	Unknown	Unk	Not Reported
Diazide (Gliclazide)	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	50 Milligram, 2 Every 1 Day(S)	Not Reported
Lopressor	S	Unknown	Unk	Not Reported
Tecta	S	Unknown	Unk	Not Reported
Cipro (Ciprofloxacin)	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	Unk	Not Reported
Gold	C	Unknown	Unk	Not Reported

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	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
	Iron Sucrose	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	8.5 Milligram, 1 Every 1 Day	Not Reported
	Venofer	C	Unknown	Unk	Not Reported
	Atenolol	C	Unknown	Unk	Not Reported
	Colchicine	C	Unknown	Unk	Not Reported
	Coversyl (Perindopril Erbumine)	C	Unknown	Unk	Not Reported
	Leucovorin	C	Unknown	Unk	Not Reported
	Levothyroxine Sodium	C	Unknown	Unk	Not Reported
	Ranitidine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	15871101	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1004862		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Hepatotoxicity; Treatment Failure	Prednisone			S	Unknown			Actavis
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	15881000	EXPEDITED (15-DAY)		HO, OT	GR-MYLANLABS-2019M1007066		56 YR	Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Increased; Drug Ineffective; Dyspnoea; Leukopenia; Microangiopathic Haemolytic Anaemia; Orthopnoea; Product Use	Alprazolam			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	10 Mg, Qd		Not Reported
	Prednisolone			S	Unknown	7.5 Milligram, Qd		Not Reported
	Citalopram			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

In Unapproved Indication; Raynaud'S Phenomenon; Renal Impairment; Scleroderma Renal Crisis; Scleroedema; Therapy Non-Responder; Thrombocytopenia; Weight Decreased	Methotrexate Captopril Captopril Etanercept Etanercept Folic Acid Folate Sodium Hydroxychloroquine Hydroxychloroquine Valsartan	S S S S S S S S S C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	15 Milligram, Qw Unk Unk Unk 5 Milligram, Qw 5 Milligram, Qw 200 Mg, Qd Unk Unk	Not Reported Not Reported Not Reported Mylan Mylan Mylan Not Reported Not Reported Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16057413	NON-EXPEDITED			US-PFIZER INC-2019103272		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Pfizer
	Methotrexate Sodium			S				Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Sulfasalazine			S				Pfizer
	Plaquenil			S		Unk		Not Reported
	Plaquenil			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16135292	EXPEDITED (15-DAY)		OT	DE-SA-2018SA251992		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Hydroxychloroquine Sulfate			S	Subcutaneous			Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Subcutaneous	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Plaquenil			S	Oral	2 Df, Qd		Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil	S	Oral	10 Mg, Qd (5mg Bid)	Sanofi
Plaquenil	S	Oral	10 Mg, Qd	Sanofi
Plaquenil	S	Oral	Unk	Sanofi
Plaquenil	S			Sanofi
Sulfasalazine	S	Oral	Unk	Not Reported
Leflunomide	S	Oral		Sanofi
Leflunomide	S	Unknown	Unk	Sanofi
Methotrexate	S	Oral	20 Mg Tablet	Not Reported
Methotrexate	S	Oral	20 Unk	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate	S	Subcutaneous	20 Mg	Not Reported
Methotrexate Sodium	S		20 Mg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Ciclosporin	S			Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk, Solution Subcutaneous	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Neoral	S	Oral		Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg/Kg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk, Solution Intravenous	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous		Not Reported
Xeljanz	C	Unknown	2 Df, Qd, 2ot	Not Reported
Xeljanz	C	Oral	10 Mg, Qd (5 Mg, Bid)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	C	Oral	5 Mg, Qd	Not Reported
Xeljanz	C	Oral	10 Mg, Qd	Not Reported
Xeljanz	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16198298	EXPEDITED (15-DAY)		OT	CA-009507513-1904CAN006267		14 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Fosamax			S	Unknown	Unk		Merck
	Vasotec			S	Unknown			Merck
	Acetazolamide			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Calcium Carbonate			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Cyclosporine			S	Unknown	Unk		Not Reported
	Iron Polymaltose			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	1 Every 1 Month, Qm		Not Reported
	Infliximab			S	Unknown	1 Every 1 Month, Qm		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Cyclophosphamide	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown		Not Reported
Insulin	S	Unknown		Not Reported
Metformin	S	Unknown		Not Reported
Nutropin (Atropine Sulfate)	S	Subcutaneous	Formulation Liquid	Not Reported
Protropin	S	Intramuscular	Formulation Liquid	Not Reported
Ranitidine	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1000 Milligrams, 1 Every 1 Months	Not Reported
Remicade	S			Not Reported
Remicade	S			Not Reported
Sulfamethoxazole	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	1 Dosage Form; Dosage Form Powder For Solution Intravenous	Not Reported
Remicade	S			Not Reported
Amlodipine	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Testosterone	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16211049	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2017SA020214		3 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency;	Hydroxychloroquine			S	Oral	5 Mg/Kg,Qd		Sanofi	
Antibody Test Positive;	Hydroxychloroquine			S				Sanofi	
Arthritis; Arthritis;	Immunoglobulins			S	Intravenous (not otherwise specified)	70 G,Unk		Not Reported	
Arthropathy; Bone Density Decreased; C-Reactive Protein Increased;	(Immunoglobulin Human Normal)								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Condition Aggravated; Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Immunoglobulins (Immunoglobulin Human Normal) Immunoglobulins (Immunoglobulin Human Normal) Methotrexate Methotrexate Naproxen Prednisone Prednisone Prednisone Isoniazid/Rifampicin Sulfasalazine Adalimumab Abatacept Actemra Actemra Anakinra Anakinra Etanercept Etanercept Infliximab Infliximab Triamcinolone Triamcinolone Orencia	S S S S S S S S S S S S S S S S S S S S S S S S S	Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Unknown Unknown Oral Oral Unknown Intravenous (not otherwise specified) Oral Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Subcutaneous Subcutaneous Subcutaneous Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Intravenous (not	70 G,Unk Unk 15 Mg/M2,Qow Unk Unk,Qw Unk Unk,Unk 5 Mg,Bid 3 Mg,Bid 1.3 Mg, Bid Unk 250 Mg,Qd Unk Unk,Unk 250 Mg,Qm 280 Mg,Qow 280 Mg, Qw 50 Mg,Qd 50 Unk 25 Mg,Qw 12.5 Mg,Qw 3 Mg/Kg,Unk 5 Mg,Unk Unk Unk,Unk Unk Unk,Unk 250 Mg,Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Sanofi Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Enbrel	S	Subcutaneous	25 Mg,Qw	Not Reported
Tocilizumab	S		250 Mg, Qd	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	280 Mg, Qcy (Every 2 Weel)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Folic Acid	C			Not Reported
Triamcinolone Hexacetonide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16226782	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110561			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Leflunomide			S				Sanofi
	Leflunomide			S		Unk		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Enbrel			S		Therapy Duration: 366.0		Not Reported
	Orencia			S		Therapy Duration: 365.0		Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C				Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16646745	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202640			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Drug Ineffective; Gait Inability; Hand Deformity; Insomnia;	Plaquenil			S		2 Df, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	2 Df, Qd		Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Pain In Extremity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Leflunomide	S	Oral	20 Mg, Qd	Sanofi
	Leflunomide	S	Oral	1 Df, Qd	Sanofi
	Arava	S	Unknown		Sanofi
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk Unk, Unk	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Actemra	S		Unk	Not Reported
	Azathioprine	S	Unknown	Unk, Unk	Not Reported
	Azathioprine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	2 Df, Qw	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown	81 Mg, Qd	Not Reported
	Tiaprofenic Acid	C	Unknown	300 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16646786	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202522		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Methotrexate			S		20 Mg, Qw		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ketorolac	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	5 Mg, Bid Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16648293	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202693		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Gait Inability; Hypogammaglobulinaemia ; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Sulfasalazine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16652291	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202820			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthritis; Blood Cholesterol Increased; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Peripheral Swelling; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Humira			S	Subcutaneous	200 Mg, Bid		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Xeljanz			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Dyclonine Hydrochloride	C	Unknown	Not Reported
Enablex [Darifenacin Hydrobromide]	C		Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Lasix [Furosemide]	C	Unknown	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Not Reported
Omnaris	C	Unknown	Not Reported
Oxyneo	C	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Not Reported
Restasis	C		Not Reported
Rituxan	C	Intravenous (not otherwise specified)	Not Reported
Synthroid	C		Not Reported
Trimethoprim	C	Unknown	Not Reported
Urispas	C		Not Reported
Vagifem	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16655165	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202784			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint	Hydroxychloroquine			S				Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling; Nausea; Pain;	Leflunomide	S						Sanofi
Rheumatoid Arthritis;	Bacitracin	S						Not Reported
Therapeutic Product Effect	Methotrexate	S						Not Reported
Decreased	Neomycin Sulfate	S						Not Reported
	Actemra	S		Subcutaneous				Not Reported
	Polymyxin B Sulfate	S						Not Reported
	Etanercept	S		Subcutaneous				Not Reported
	Prednisone	C		Intramuscular				Not Reported
	Xeljanz	C		Oral	2 Df, Bid, 5mg			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16656988	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202955		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein	Hydroxychloroquine			S		200 Mg, Qd		Sanofi
Abnormal; Drug	Arava			S		1 Df, Qd		Sanofi
Hypersensitivity; Drug	Methotrexate			S		25 Mg		Not Reported
Ineffective; Drug	Sulfasalazine			S		1500 Mg		Not Reported
Intolerance; Hepatitis;	Actemra			S				Not Reported
Hypersensitivity; Red	Enbrel			S				Not Reported
Blood Cell Sedimentation	Orencia			S				Not Reported
Rate Abnormal;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Rheumatoid Factor	Anakinra			C				Not Reported
Positive; Synovitis;								
Vomiting								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16716102	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190803947			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Otezla			S	Oral			Celgene
Arthritis; Blood Cholesterol	Actemra			S	Unknown			Not Reported
Increased; Bone Erosion;	Arava			S	Oral			Not Reported
Bronchitis;	Azathioprine			S	Unknown			Not Reported
Contraindicated Product								

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Administered; Dizziness;	Cimzia	S	Subcutaneous	Not Reported
Drug Hypersensitivity;	Enbrel	S	Unknown	Not Reported
Drug Ineffective; Drug	Humira	S	Subcutaneous	Not Reported
Intolerance; Drug-Induced	Methotrexate	S	Oral	Not Reported
Liver Injury; Exostosis;	Minocycline Hydrochloride	S	Unknown	Not Reported
Foot Deformity;	Orencia	S	Unknown	Not Reported
Headache; Hepatic	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Cirrhosis; Hypertension;	Rituxan	S	Intravenous drip	Not Reported
Infection; Joint Dislocation;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Joint Stiffness; Malaise;	Rituxan	S	Intravenous drip	Not Reported
Nasopharyngitis; Nausea;	Simponi	S	Subcutaneous	Not Reported
Off Label Use;	Sirukumab	S	Unknown	Not Reported
Osteoarthritis;	Stelara	S	Subcutaneous	Not Reported
Osteoporosis; Pneumonia;	Sulfasalazine	S	Unknown	Not Reported
Psoriasis; Synovitis;	Xeljanz	S	Oral	Not Reported
Tachycardia; Upper	Ciclosporin	S	Unknown	Not Reported
Respiratory Tract Infection	Telmisartan	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported
	Amlodipine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Amitriptyline	C	Oral	Not Reported
	Betamethasone	C	Topical	Not Reported
	Betamethasone Dipropionate	C	Unknown	Not Reported
	W/Calcipotriol	C	Unknown	Not Reported
	Melatonin	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

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Dilaudid	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16957606	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1125473		70 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congestive Cardiomyopathy; Disseminated Varicella Zoster Vaccine Virus Infection; Gastrointestinal Disorder; Leukopenia; Lung Disorder; Multiple Organ Dysfunction Syndrome; Thrombocytopenia	Methotrexate			S	Unknown	2.5 Milligram Daily; Administered 6 Days A Week; Ongoing For 3 Years		Barr
	Prednisone			S	Unknown	10 Milligram Daily; Tapered One Month Prior To Presentation		Actavis
	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Not Reported
	Zostavax li			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	16971655	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20191006447			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Otezla			S	Oral	60 Milligram		Celgene
	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown	150 Milligram		Not Reported
	Enbrel			S	Unknown	50 Milligram		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous	125 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Sulfasalazine			C	Unknown	2 Gram		Not Reported

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Detailed Report

Treatment Failure;
Vomiting; White Blood Cell
Count Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17026290	EXPEDITED (15-DAY)		HO	CA-ROCHE-2459593		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Actemra			S	Unknown			Not Reported
Abdominal Pain Upper;	Enbrel			S	Unknown			Not Reported
Alopecia; Arthralgia; Bone	Humira			S	Subcutaneous			Not Reported
Pain; Burning Sensation;	Hydroxychloroquine			S	Unknown	Therapy Duration 5.0		Not Reported
Choking; Cough; Drug						Month(S)		
Ineffective; Drug	Methotrexate			S	Unknown	Therapy Duration 4.0		Not Reported
Intolerance; Facial Pain;						Month(S)		
Fatigue; Fibromyalgia;	Orencia			S	Unknown			Not Reported
Headache; Hot Flush;	Xeljanz			S	Oral			Not Reported
Hypoaesthesia; Immune	Xeljanz			S	Oral	Therapy Duration -229.0		Not Reported
System Disorder;	Morphine			C	Unknown			Not Reported
Insomnia; Joint Range Of	Tylenol			C	Unknown			Not Reported
Motion Decreased;								
Lipoma; Melanocytic								
Naevus; Nasal Discomfort;								
Nausea; Night Sweats;								
Oropharyngeal								
Discomfort; Osteoporosis;								
Pain; Pain In Extremity;								
Pain In Jaw; Peripheral								
Coldness; Platelet Count								
Decreased; Rhinorrhoea;								
Skin Mass								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17303675	EXPEDITED (15-DAY)		DE	CA-009507513- 2001CAN007751		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort	Fosamax			S	Unknown	70 Milligram, 1 Every 1 Weeks		Merck

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Flovent	S	Unknown	Dosage Form: Not Specified, Unk	Not Reported
Albuterol Sulfate (+) Ipratropium Bromide	S	Unknown	Dosage Form: Solution Inhalation, Unk	Not Reported
Lasix (Furosemide Sodium)	S	Unknown	40 Milligram, Unk; Dosage Form: Not Specified	Not Reported
Lipitor	S	Unknown	10 Milligram, Unk; Dosage Form: Not Specified	Not Reported
Losec (Omeprazole Magnesium)	S	Oral	20 Milligram, Unk; Dosage Form: Not Specified	Not Reported
Metformin	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
Nitrazadon	S	Unknown	10 Milligram, Unk	Not Reported
Plaquenil	S	Unknown	300 Milligram, 1 Every 1 Days	Not Reported
Prednisone	S	Unknown	5 Milligram, 1 Every 1 Days, Dosage Form: Not Specified	Not Reported
Salmeterol Xinafoate	S	Unknown	Unk	Not Reported
Tylenol	S	Unknown	500 Milligram, Unk; Dosage Form: Not Specified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17518925	EXPEDITED (15-DAY)		OT	CA-ROCHE-2564559		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Blood Cholesterol Increased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Synovitis	Apo-Azathioprine			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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Etanercept	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Parenteral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Tofacitinib	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17570987	NON-EXPEDITED			US-PFIZER INC-2020121578		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Enbrel			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, 0, 2, 6 Wks, Then Every 8 Wks		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 8 Weeks		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 7 Weeks		Not Reported	
	Humira			S		Unk		Not Reported	

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	Hydroxychloroquine	S	Unk	Not Reported
	Otrexup	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17663764	EXPEDITED (15-DAY)		OT	US-ROCHE-2580025			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Mycophenolate Mofetil			S	Unknown			Not Reported
Abnormal Dreams;	Mycophenolic Acid			S	Unknown			Not Reported
Alopecia; Anaemia;	Methotrexate			S	Unknown			Not Reported
Cytopenia; Depressed	Prednisone			S	Unknown			Not Reported
Mood; Dizziness; Dry	Methylprednisolone			S	Unknown			Not Reported
Mouth; Fatigue;	Hydroxychloroquine			S	Unknown			Not Reported
Gastrointestinal Disorder;	Doxycycline			S	Unknown			Not Reported
Hirsutism; Infection;								
Insomnia; Leukopenia;								
Palpitations;								
Transaminases Increased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17678874	EXPEDITED (15-DAY)		LT, OT	FR-ADVANS PHARMA-202004002607			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome;	Hydroxychloroquine			S		400 Mg, Qd (Film-Coated Tablet)		Concordia
Bronchopulmonary	Heparine			C		Unk		Not Reported
Aspergillosis; Catheter	Norepinephrine			C		Unk		Not Reported
Bacteraemia; Off Label Use;	Furosemide			C		Unk		Not Reported
Pneumomediastinum;	Insulin			C		Unk		Not Reported
Pneumonia Bacterial;								
Pneumonia Bacterial;								
Renal Failure; Shock								
Haemorrhagic								

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17726960	EXPEDITED (15-DAY)		HO, OT	FR-ADVANZ PHARMA-202004004250			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Chondrocalcinosis; Off Label Use; Systemic Inflammatory Response Syndrome	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film-Coated Tablet		Concordia	
	Hydroxychloroquine			S		400 Mg, Qd, Film-Coated Tablet		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17727561	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1042619		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported	
	Lasilix /00032601/			S	Intravenous (not otherwise specified)	2 Dosage Form, Qd		Mylan	
	Plaquenil /00072603/			S	Oral	Unk		Mylan	
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Mylan	
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Mylan	
	Noradrenaline /00127501/			C	Intravenous (not otherwise specified)	Unk		Mylan	
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Mylan	
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Qd		Mylan	
	Transipeglib			C	Oral	Unk		Mylan	
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Mylan	
	Nimbex /01302502/			C	Intravenous (not otherwise specified)	Unk		Mylan	

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Ultibro Breezhaler	C	Respiratory (inhalation)	Unk	Mylan
Seresta	C	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17736227	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1043094		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sudden Death	Levofloxacin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported	
	Tacrolimus			S		Unk		Mylan	
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Mylan	
	Ceftriaxona /00672201/			C	Unknown	Unk		Mylan	
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Mylan	
	Prednisona			C	Oral	20 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17744110	EXPEDITED (15-DAY)		LT, OT	FR-MYLANLABS-2020M1043359		18 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Diabetic Metabolic Decompensation; Haemoglobin Decreased; Hepatocellular Injury; Inflammation; Pyrexia; Respiratory Disorder	Midazolam			S	Intravenous (not otherwise specified)	5 Mg/ML, Qd		Not Reported	
	Lovenox			S	Subcutaneous	0.6 ML, Qd		Mylan	
	Hydroxychloroquine Sulfate			S	Unknown	1200 Milligram, Qd		Mylan	
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan	
	Omeprazole			S	Intravenous (not otherwise specified)	20 Milligram, Qd		Mylan	
	Omeprazole			S	Intravenous (not otherwise specified)	40 Milligram, Qd		Mylan	
	Loxen /00890702/			S	Intravenous (not otherwise specified)	30 Milligram, Qd		Mylan	

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			otherwise specified)		
Movicol /01749801/	S	Other	2 Df Bag		Mylan
Novorapid	C	Intravenous (not otherwise specified)	Unk		Mylan
Omeprazol 1 A Pharma	C	Other	20 Mg, Qd		Mylan
Paracetamol	C	Other	4 G, Qd		Mylan
Paracetamol	C				Mylan
Diffu K	C	Unknown	3.6 Gram, Qd		Mylan
Lasilix /00032601/	C		30 Milligram, Qd		Mylan
Doliprane	C		Unk		Mylan
Doliprane	C				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17760562	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020183153			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Pneumonitis; Psoriasis; Urticaria	Infliximab			S	Unknown	Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Methylprednisolone Acetate			S		Unk		Pfizer
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17766483	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020185574		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Tocilizumab			S	Intravenous (not	600 Mg, Single		Not Reported

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Unapproved Indication				otherwise specified)					
	Hydroxychloroquine		S	Oral	400 Mg, 1x/Day				Not Reported
	Hydroxychloroquine		S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17782613	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593919		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Actemra			S	Unknown			Not Reported
Drug Hypersensitivity;	Rituximab			S	Intravenous drip			Not Reported
Drug Ineffective; Drug	Mycophenolate Mofetil			S	Unknown			Not Reported
Intolerance; Off Label Use;	Mycophenolate Mofetil			S				Not Reported
Psoriatic Arthropathy;	Arava			S	Unknown			Not Reported
Rash; Rheumatoid	Enbrel			S	Unknown			Not Reported
Arthritis; Sciatica;	Gold			S	Unknown			Not Reported
Sinusitis; Therapeutic	Hydroxychloroquine			S	Unknown			Not Reported
Product Effect Incomplete;	Humira			S	Subcutaneous			Not Reported
Treatment Failure	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Piroxicam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17787717	EXPEDITED (15-DAY)		DE	MX-ADVANSZ PHARMA-202004005019			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Haemodynamic Instability; Off Label Use	Hydroxychloroquine	S	200 Mg, Bid (Q12h)	Concordia
	Hydroxychloroquine	S		Concordia
	Furosemide	C		Not Reported
	Clarithromycin	C		Not Reported
	Ceftriaxone	C		Not Reported
	Enoxaparin	C		Not Reported
	Methylprednisolone	C		Not Reported
	Meropenem	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17787749	EXPEDITED (15-DAY)		DS, HO, OT	CA-SAMSUNG BIOEPIS-SB-2020- 15795		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Aminotransferase	Infliximab			S	Oral	Unknown		Not Reported	
Increased; Arthralgia; Aspartate	Adalimumab			S	Subcutaneous			Not Reported	
Aminotransferase	Actemra			S	Unknown			Not Reported	
Increased; Basal Cell Carcinoma; Blood	Actemra			S	Unknown			Not Reported	
Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C- Reactive Protein	Alendronate Sodium			S	Unknown			Not Reported	
Increased; Condition	Alendronate Sodium			S	Unknown			Not Reported	
Aggravated; Drug	Alendronic Acid			S	Unknown			Not Reported	
Eruption; Drug	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported	
Hypersensitivity; Drug	Apo-Ibuprofen			S	Oral	Unknown		Not Reported	
Ineffective; Drug	Apo-Leflunomide			S	Oral			Not Reported	
Intolerance; Drug	Apo-Leflunomide			S	Oral			Not Reported	
Tolerance Decreased; Enthesopathy; Erythema;	Apo-Leflunomide			S	Oral			Not Reported	
Granuloma Skin;	Apremilast			S	Unknown	Unknown		Not Reported	
Headache;	Apremilast			S	Unknown			Not Reported	
Hypercalcaemia;	Apremilast			S				Not Reported	
Hypersensitivity;	Arava			S	Unknown	Unknown		Not Reported	
Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Cimzia			S	Subcutaneous	Unknown		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Daily Activities;	Cyclosporin	S	Unknown	Unknown	Not Reported
Musculoskeletal Disorder;	Enbrel	S	Unknown		Not Reported
Musculoskeletal Stiffness;	Enbrel	S	Unknown		Not Reported
Nausea; Off Label Use;	Enbrel	S	Unknown		Not Reported
Pain; Panniculitis;	Enbrel	S	Unknown		Not Reported
Peripheral Swelling;	Enbrel	S	Subcutaneous	Unknown	Not Reported
Product Use Issue;	Humira	S	Subcutaneous		Not Reported
Psoriatic Arthropathy;	Hydroxychloroquine	S	Oral		Not Reported
Rash; Rash Pruritic; Red	Hydroxychloroquine	S	Oral		Not Reported
Blood Cell Sedimentation	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Rate Increased;	Ibuprofen	S	Oral		Not Reported
Rheumatoid Arthritis;	Leflunomide	S	Unknown		Not Reported
Rheumatoid Nodule; Skin	Leflunomide	S	Oral		Not Reported
Necrosis; Skin Ulcer;	Methotrexate	S	Oral		Not Reported
Synovitis; Tendonitis;	Methotrexate	S	Oral		Not Reported
Tenosynovitis;	Methotrexate	S	Oral		Not Reported
Therapeutic Product Effect	Methotrexate	S	Oral		Not Reported
Decreased; Therapeutic	Methotrexate	S	Oral		Not Reported
Product Effect Incomplete;	Methotrexate	S	Oral		Not Reported
Tongue Disorder; Ulcer	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Motrin [Ibuprofen]	S	Oral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Subcutaneous	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituxan	S	Unknown		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Unknown	Not Reported
Stelara	S	Subcutaneous	Unknown	Not Reported
Sulfasalazine	S	Endocervical		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Tocilizumab	S	Unknown		Not Reported
Codeine	S	Unknown	Unknown	Not Reported
Otezla	S	Unknown	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	Unknown	Not Reported
Colchicine	C	Oral	Unknown	Not Reported
Dexilant	C	Oral	Unknown	Not Reported
Febuxostat	C	Unknown	Unknown	Not Reported

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	Folic Acid	C	Unknown	Unknown	Not Reported
	Gravol	C	Unknown	Unknown	Not Reported
	Mogadon	C	Oral		Not Reported
	Nitrazepam	C	Unknown		Not Reported
	Oxycodone	C	Unknown	Unknown	Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisolone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Uloric	C	Unknown		Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788081	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-024673		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Quetiapine Arrow Lp 50 Mg Prolonged Release Tablet			S	Oral	100 Milligram, Once A Day		Aurobindo	
	Zithromax			S	Oral	250 Milligram, Once A Day		Not Reported	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788113	EXPEDITED (15-DAY)		HO	ES-ACCORD-181994		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Azithromycin			S	Oral	500 Mg Day		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788220	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2598905		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein	Actemra			S	Unknown			Not Reported
Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Unknown			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597595		34 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Synovitis	Tocilizumab			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Prednisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596424		72 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Oral Candidiasis; Pain; Peripheral Swelling;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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Rheumatoid Arthritis;	Leflunomide	S	Oral	Not Reported
Swelling; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Product Effect Decreased;	Methotrexate	S	Subcutaneous	Not Reported
Thyroid Neoplasm;	Methotrexate	S	Subcutaneous	Not Reported
Toxicity To Various Agents	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788436	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020192176		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fall; Gait Inability; Malaise;	Methotrexate Sodium			S	Unknown	Unk		Pfizer
Paralysis; Spinal Fracture	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788502	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234906		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Condition	Acetaminophen			S	Unknown			Not Reported
Aggravated; Drug	Methotrexate			S	Subcutaneous	25 Milligram		Barr
Ineffective; Drug	Methotrexate			S	Subcutaneous	25 Milligram		Barr
Intolerance; Eye Disorder;	Prednisone			S	Unknown			Actavis
Eye Pain; Fatigue;	Prednisone			S	Unknown	7.5 Milligram		Actavis
Glaucoma; Inflammation;	Actemra			S	Unknown			Not Reported
Lacrimation Increased;	Dilaudid			S	Unknown			Not Reported
Pain; Photophobia; Post								
Procedural Complication;								
Rheumatoid Arthritis;								
Synovitis								

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	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

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15-May-2020	17789376	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247219		60 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17790293	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR- 001539			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiotoxicity; Dysphagia; Musculoskeletal Toxicity; Myopathy Toxic; Toxicity To Various Agents; Weight Decreased	Chloroquine			S	Unknown	200 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca
	Acetylsalicylic Acid			C	Unknown	75 Milligram, Qd		Not Reported
	Clopidogrel			C	Unknown	75 Milligram, Qd		Not Reported
	Fenofibrate			C	Unknown	100 Milligram, Qd		Not Reported
	Ranitidine			C	Unknown	300 Milligram, Qd		Not Reported
	Clobetasol			C	Unknown	Unk, Qd		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

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15-May-2020	17790373	EXPEDITED (15-DAY)		OT	NVSC2020KR130316		59 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Optic Neuritis; Retinopathy	Hydroxychloroquine			S	Unknown	300 Mg, Qd		Novartis	
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported	
	Prednisolone			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17790411	EXPEDITED (15-DAY)		OT	NVSC2020IT130474		43 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Pyrexia; Systemic Lupus Erythematosus	Mycophenolate Mofetil			S	Unknown	Unk Unk, Qd		Novartis	
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported	
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported	
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported	
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported	
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported	
	Prednisone			S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported	
	Tacrolimus			S	Unknown	Unk Unk, Qd		Not Reported	
	Methylprednisolone			C		Unk (Pulses)		Not Reported	

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	Rituximab		C	Unknown	Unk			Not Reported	
	Immunoglobulin I.V		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791337	EXPEDITED (15-DAY)		HO, OT	FR-SA-2020SA125110		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Off Label Use; Ventricular Fibrillation	Plaquenil			S	Oral			Sanofi	
	Plaquenil			S				Sanofi	
	Lasilix			S	Oral	Unk		Sanofi	
	Risordan			S	Intravenous (not otherwise specified)			Not Reported	
	Irbesartan			S	Oral	Unk		Sanofi	
	Carvedilol			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791355	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2020-GB- 001382			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrasystoles; Palpitations	Hydroxychloroquine			S	Unknown	Unk		Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791635	EXPEDITED (15-DAY)		OT	ES-ACCORD-182005		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported	
	Azithromycin			S	Oral	500 Mg Dia		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791638	EXPEDITED (15-DAY)		OT	GB-ACCORD-181984		48 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrasystoles; Palpitations	Hydroxychloroquine			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791654	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234484		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Nausea; Pain In Extremity; Peripheral Swelling	Prednisone			S	Unknown				Actavis
	Prednisone			S					Actavis
	Methotrexate			S	Subcutaneous				Barr
	Methotrexate			S					Barr
	Arava			S	Oral				Not Reported
	Arava			S					Not Reported
	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine Sulfate			S	Oral				Not Reported
	Hydroxychloroquine Sulfate			S					Not Reported
	Infliximab			S	Unknown				Not Reported
	Infliximab			S					Not Reported
	Rituximab			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown	1000 Milligram Daily;			Not Reported
	Sulfasalazine			S					Not Reported
Xeljanz	Xeljanz			S	Oral	10 Milligram Daily;			Not Reported
	Xeljanz			S					Not Reported
	Atorvastatin			C	Unknown				Not Reported
	Pantoloc [Pantoprazole]			C	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791682	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1046807		74 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg Dia		Not Reported
	Dolquine			S	Oral	400 Mg Dia		Mylan
	Kaletra			S	Oral	2u / 12 H		Mylan
	Kaletra			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791698	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1234911		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling; Psychiatric Symptom; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Methotrexate			S	Unknown			Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Unknown	14 Milligram Daily;		Not Reported
	Dilaudid			C	Unknown	12 Milligram Daily;		Not Reported
	Furosemide			C	Unknown			Not Reported
	Hydromorph Contin			C	Unknown	54 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791711	EXPEDITED (15-DAY)		OT	ES-ACCORD-181713		51 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Neutropenia; Off Label Use	Hydroxychloroquine	S	Oral	400 Mg / 12h From 14-Apr-2020 To 17-Apr-2020	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2gr/24h	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg / 24 H From 11-Apr-2020 To 12-Apr-2020, 400 Mg / 12 H From 14-Apr-2020 To 17-Apr-2020	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595998		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Subcutaneous			Not Reported
	Zostavax			C	Subcutaneous	Powder For Suspension Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791733	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597016		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Caffeine			C				Not Reported
	Arava			C				Not Reported
	Folic Acid			C				Not Reported
	Leflunomide			C				Not Reported
	Methotrexate			C				Not Reported
	Naproxen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791743	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-15914			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection;	Infliximab			S	Unknown	Unknown		Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Prednisone			S	Unknown	Unknown		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown Powder For Solution Intravenous		Not Reported

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Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Enbrel	S	Unknown	Unknown	Not Reported
	Acetaminophen	C	Unknown	Unknown	Not Reported
	Acidophilus	C	Unknown	Unknown	Not Reported
	Aspirin	C	Unknown	Unknown	Not Reported
	Calcium	C	Unknown	Unknown	Not Reported
	Deflazacort	C	Unknown	Unknown	Not Reported
	Dilaudid	C	Unknown	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Unknown	Not Reported
	Hydromorphone Hydrochloride	C	Unknown	Unknown	Not Reported
	Januvia	C	Unknown	Unknown	Not Reported
	Kenalog	C	Unknown	Unknown	Not Reported
	Lidocaine	C	Topical	Unknown	Not Reported
	Metronidazole	C	Unknown	Unknown	Not Reported
	Nitroglycerin	C	Unknown	Unknown	Not Reported
	Pantoloc	C	Unknown	Unknown	Not Reported
	Pregabalin	C	Unknown	Unknown	Not Reported
	Risedronate	C	Unknown	Unknown	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unknown	Not Reported
	Salbutamol	C	Unknown	Unknown	Not Reported
	Triamcinolone	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17791808	DIRECT	Y	LT			39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral			Sandoz	
	Acetaminophen 650 Mg Po			C				Not Reported	
	Maalox-Plus 30 MI Po			C				Not Reported	

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Albuterol Mdi	C	Not Reported
Enoxaparin 40mg Sc	C	Not Reported
Levofloxacin 750mg Po	C	Not Reported
Melatonin 3mg	C	Not Reported
Ondansetron 4mg Ivp	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792081	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANSZ PHARMA-202004005069			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epstein-Barr Virus Infection Reactivation; Klebsiella Infection; Off Label Use; Pneumonia Adenoviral; Pneumonia Escherichia	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Cyclophosphamide			S	Unknown	14.5 Mg/Kg Days -6 And -5		Not Reported
	Cyclophosphamide			S	Unknown	500 Mg/Kg Days 3 And 4		Not Reported
	Fludarabine Phosphate			S	Unknown	30 Mg/M2 From Days -6 Through -2		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S				Not Reported
	Mesalazine			S	Unknown	1.2 G, Bid Q12h		Not Reported
	Mesalazine			S				Not Reported
	Azathioprine			S	Unknown	150 Mg, Qd		Not Reported
	Azathioprine			S				Not Reported
	Busulfan			S	Intravenous (not otherwise specified)	Unk, Qd On Days -4, -3,-2		Not Reported
	Sirolimus			S	Unknown	Unk		Not Reported
	Basiliximab			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792157	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234794		59 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hepatitis	Azitromicina (7019a)	S	Oral	500 Mg Day	Not Reported
	Hidroxiclороquina (2143a)	S	Oral	400 Mg Day	Teva
	Hidroxiclороquina (2143a)	S			Teva
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 G, Day	Not Reported
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792348	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020192350		96 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Extrasystoles; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S		400 Mg, 1x/Day		Not Reported	
	Novorapid			C				Not Reported	
	Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch			C				Not Reported	
	Cardirene			C		75 Mg		Not Reported	
	Pantorc			C		20 Mg		Not Reported	
	Lantus			C				Not Reported	
	Metoprololo			C		50 Mg		Not Reported	
	Dobetin [Cyanocobalamin]			C				Not Reported	
	Normix			C				Not Reported	
	Lasix [Furosemide]			C				Not Reported	
	Deltacortene			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792351	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235702			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Fatigue; Glossodynia; Pemphigus;	Methotrexate			S	Unknown			Barr	

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Systemic Lupus Erythematosus	Prednisone	S	Unknown	Actavis
	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Reactine (Cetirizine)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235646			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Fibromyalgia; Hernia; Hypertension; Hypoglycaemia; Lymphoma; Thyroid Disorder	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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Remicade	S	Unknown	Not Reported
Rituximab	S	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792436	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1234988			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Disorder; Bronchiectasis; Bursitis; Bursitis Infective; Crying; Erythema; Gastrointestinal Disorder; Infection; Joint Range Of Motion Decreased; Localised Infection; Osteoporosis; Peripheral Vascular Disorder; Photosensitivity Reaction; Pneumonia; Renal Failure; Respiratory Tract Infection; Rheumatoid Arthritis; Skin Discolouration; Skin Ulcer; Staphylococcal Infection; Swelling; Synovitis; Tenosynovitis; Therapeutic Product Effect Incomplete	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Acidophilus			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Deflazacort			C	Unknown			Not Reported
	Dilaudid			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Januvia			C	Unknown			Not Reported
Kenalog [Triamcinolone Acetonide]			C	Unknown			Not Reported	
Metronidazole			C	Unknown			Not Reported	
Nitroglycerin			C	Unknown			Not Reported	

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Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Pregabalin	C	Unknown	Not Reported
Risedronate	C	Unknown	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported
Salbutamol	C	Unknown	Not Reported
Triamcinolone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792459	EXPEDITED (15-DAY)		LT, OT	JP-HQ SPECIALTY-JP-2020INT000054		38 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Atrioventricular Block First Degree; Covid-19 Pneumonia; Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Ventricular Fibrillation; Viral Myocarditis	Dexmedetomidine Hydrochloride			S	Unknown	Unk		Hq Specialty
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Favipiravir			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Ciclesonide			C	Unknown	Unk		Not Reported
	Methylprednisolone			C	Unknown	1 Mg/Kg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792537	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20171028710		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fracture; Incorrect Route Of Product Administration; Infection; Pneumonia; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

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	Celebrex	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate Sodium	S	Intra-arterial	Not Reported
	Methotrexate Sodium	S	Intra-articular	Not Reported
	Naproxen Sodium	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792663	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233509		35 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported	
	Rapamune			C	Oral	1 Mg		Not Reported	
	Rapamune			C				Not Reported	
	Enoxaparina (2482a)			C	Subcutaneous	40 Mg Day		Not Reported	
	Deflazacort (2546a)			C	Oral	6 Mg		Not Reported	
	Deflazacort (2546a)			C				Not Reported	
	Deflazacort (2546a)			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792744	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020191417		56 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypoacusis	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792762	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020191421		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Azithromycin			S				Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Ceftriaxone			S				Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792773	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020191268		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Off Label Use; Product Use In Unapproved Indication; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Pfizer	
	Noradrenaline Hospira			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	Unk		Not Reported	
	Loxen [Nicardipine Hydrochloride]			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	
	Sufentanil			C		Unk		Not Reported	
	Nimbex [Cisatracurium Besilate]			C		Unk		Not Reported	
	Hypnovel [Midazolam Hydrochloride]			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17793014	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123123			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Fatigue; Joint Swelling; Leukopenia; Nausea; Pain In Extremity; Peripheral Swelling; Vomiting; Weight Decreased	Arava			S	Unknown	1 Every 1 Day		Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown	1 Every 1 Day		Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown	2 Every 1 Day		Sanofi	
	Methotrexate			S	Unknown	1 Every 1 Week		Not Reported	
	Adalimumab			S	Subcutaneous	1 Df		Not Reported	
	Calcium			C				Not Reported	
	Fentanyl			C				Not Reported	
	Folic Acid			C				Not Reported	
	Magnesium			C				Not Reported	
	Naproxen Sodium			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Potassium			C				Not Reported	
	Tramadol			C				Not Reported	
	Vitamin D [Colecalciferol]			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17793016	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123056			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Interstitial Lung Disease; Vomiting	Leflunomide			S	Oral	10 Mg, Qd		Sanofi	
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported	
	Sulfasalazine			S	Unknown	500 Mg, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Sanofi	
	Azathioprine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17793017	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123029			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous	40 Mg		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral	20 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17793233	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234720		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported

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Folic Acid	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown 200 Milligram Daily;	Not Reported
Hydroxychloroquine Sulfate	S	Unknown 400 Milligram Daily;	Not Reported
Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17793424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234471			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure; Wound	Methotrexate			S	Intra-arterial	25 Milligram Daily;		Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine (Cetirizine)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown	2 Gram Daily;	Not Reported
	Xeljanz	C	Unknown		Not Reported

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15-May-2020	17793971	EXPEDITED (15-DAY)	HO		CA-ROCHE-2598160			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17793974	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1234505		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety Disorder; Confusional State; Hepatic Steatosis; Infection; Memory Impairment; Nausea; Nightmare; Pain; Polymyalgia Rheumatica; Visual Impairment	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Acetaminophen			C				Not Reported
	Macrobid [Clarithromycin]			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794208	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2020M1047539			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	600 Mg, Qd		Mylan	
	Oxygen			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794230	EXPEDITED (15-DAY)		CA	DE-MYLANLABS-2020M1047544			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Talipes	Prednisolone			S	Transplacental	Unk		Not Reported	
	Certolizumab			S	Transplacental	Unk		Mylan	
	Hydroxychloroquine			S	Transplacental	Unk		Mylan	
	Sulfasalazine			S	Transplacental	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794256	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2020M1047894		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Metilprednisolona /00049601/			S	Intravenous (not otherwise specified)	250 Milligram, Qd		Mylan	
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan	
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan	
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram, Qd		Mylan	

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Dolquine			S	Oral	200 Milligram, Bid			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794348	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1047857		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Azithromycin			S				Not Reported	
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan	
	Hidroxicloroquina /00072601/			S				Mylan	
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd 2 Gr Dia		Mylan	
	Ceftriaxona /00672201/			S				Mylan	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Mylan	
	Tocilizumab			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794351	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1047666		83 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Intentional Product Misuse; Off Label Use	Trazodone			S	Oral	1 Dosage Form, Qd (1 Df, Qd , 1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The)		Not Reported	
	Olanzapine			S	Oral	1 Dosage Form, Qd (1 Df Qd, 1/2 Tablet 2x/Day, Treatment Was Suspended For 2 Days 11/04 And 12/04)		Mylan	
	Plaquenil /00072603/			S	Oral	Unk (Day 1: 400mg 2x/D; Day 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg; 08/04 To 10/04)		Mylan	

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Clexane	C		Unk	Mylan
Perindopril	C		1 Dosage Form, Qd (1 Df, Qd)	Mylan
Movicol /01749801/	C		1 Dosage Form, Qd (1 Df, Qd)	Mylan
L-Thyroxine /00068001/	C		1 Dosage Form, Qd (1 Df, Qd)	Mylan
Metformin	C		2 Dosage Form, Qd (2 Df, Qd)	Mylan
Prolopa	C		0.5 Dosage Form, Qd (0.5 Df, Qd)	Mylan
Contramal	C		1 Dosage Form, Prn (As Necessary)	Mylan
Kalium /00031401/	C	Oral	Unk	Mylan
Algostase Mono	C		3 Dosage Form, Qd (3 Df, Qd)	Mylan
Pradaxa	C		Unk	Mylan
Uni Diamicon	C		60 Milligram, Bid (60 Mg, Bid)	Mylan
Magnetop /00434501/	C	Oral	450 Milligram, Qd (450 Mg, Qd)	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794561	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235275			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastroesophageal Reflux Disease; Pain; Skin Irritation; Weight Increased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

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Ibuprofen			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794844	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234509			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastrooesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Ibuprofen			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794857	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-014019		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage; Vessel Puncture Site Haemorrhage	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Dia		Bausch And Lomb	
	Enoxaparina			S	Subcutaneous			Not Reported	
	Hidroxiclороquina			S	Oral			Not Reported	
	Acetylsalicylate Lysine			S	Intravenous (not otherwise specified)	200 Mg, One Total		Not Reported	
	Adiro			S	Oral	500 Tablets,1 Cp Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794860	EXPEDITED (15-DAY)		OT	US-SA-2020SA122902		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During	Hydroxychloroquine			S				Sanofi	

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Pregnancy; Lupus	Prednisone	S	Not Reported
Nephritis; Off Label Use;	Lovenox	S	Sanofi
Proteinuria; Treatment	Sulfamethoxazole/Trimethoprim	S	Not Reported
Noncompliance	Mycophenolate Mofetil	S	Not Reported
	Azathioprine	S	Not Reported
	Tacrolimus	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123326		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease	Arava			S		Unk		Sanofi
	Methotrexate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Acetylsalicylic Acid			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Lantus			C	Subcutaneous	Unk		Not Reported
	Lozide [Gliclazide]			C		Unk		Not Reported
	Metformin			C		Unk		Not Reported
	Naproxen			C		Unk		Not Reported
	Prednisone			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122626		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug	Hydroxychloroquine Sulfate			S				Sanofi
	Methotrexate			S				Not Reported

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Ineffective; Hepatic	Leflunomide	S				Sanofi
Enzyme Increased; Loss	Actemra	S				Not Reported
Of Personal Independence	Enbrel	S				Not Reported
In Daily Activities;	Humira	S	Subcutaneous	Unk		Not Reported
Pneumonia; Pulmonary	Orencia	S				Not Reported
Fibrosis	Remicade	S				Not Reported
	Rituximab	S	Intravenous (not otherwise specified)			Not Reported
	Prednisone	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794873	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123060			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial	Leflunomide			S	Oral	Unk		Sanofi
Lung Disease; Joint	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd (1 Every 1 Day)		Sanofi
Swelling; Treatment	Methotrexate			S	Unknown	25 Mg, Qw (1 Every 1 Week)		Not Reported
Failure	Sulfasalazine			S	Unknown	1 G, Bid (2 Every 1 Day)		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous drip	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794883	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123045		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption; Drug	Leflunomide			S	Unknown	2 Df, Qd		Sanofi
Ineffective; Fatigue; Loose	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
Body In Joint; Off Label	Naproxen			S	Unknown			Not Reported
Use; Osteoporotic	Prednisone			S	Unknown			Not Reported
Fracture; Pain; Synovitis								

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Actemra	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794893	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1234722		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Diverticulitis; Drug Ineffective; Skin Atrophy; Skin Laceration; Wound	Prednisone			S	Unknown	2.5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab/Vorhyaluronidase Alfa			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			C	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Humira			C	Unknown			Not Reported
	Indapamide			C	Oral	1.25 Milligram Daily;		Not Reported
	Naproxen			C	Unknown			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Pantoloc [Pantoprazole]			C	Oral	40 Milligram Daily;		Not Reported
	Perindopril			C	Unknown	2 Milligram Daily;		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17794900	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1234926		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Cough; Disease Progression; Drug Ineffective; Gait Disturbance; Immobile; Malaise	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Arava			S	Unknown	40 Milligram Daily;		Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported	
	Naproxen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17795162	EXPEDITED (15-DAY)		DE, OT	ES-BAUSCH-BL-2020-014022		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Dexametasona			S	Intravenous (not otherwise specified)			Bausch And Lomb	
	Dexametasona			S	Intravenous (not otherwise specified)	Dose Reduced		Bausch And Lomb	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg In Total		Not Reported	
	Hidroxicloroquina			S	Oral			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported	
	Enoxaparina			S	Subcutaneous			Not Reported	
	Enoxaparina			S	Subcutaneous	Dose Reduced		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17795175	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020195127		71 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported	
	Tocilizumab			S				Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17795257	EXPEDITED (15-DAY)		HO, LT, OT	JP-INSUD PHARMA-2004JP00069			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Disorder; Hormone Level Abnormal; Hypogonadism; Infarction; Maternal Exposure During Pregnancy; Off Label Use; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Proteinuria; Vaginal Haemorrhage	Progesterone			S	Vaginal	300 Mg		Xiromed	
	Estrasorb			S	Transdermal			Exceltis Usa	
	Tacrolimus Monohydrate			S	Unknown	4 Mg		Not Reported	
	Dydrogesterone			S	Oral	15 Milligram Daily		Not Reported	
	Prednisolone			S	Unknown	7.5 Mg		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797261	DIRECT	Y	LT			85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	Other Frequency:Bid X 1day,Then Qd;		Sandoz	
	Acetaminophen 325 Mg			C				Not Reported	
	Azithromycin 250 Mg			C				Not Reported	
	Baclofen 20mg			C				Not Reported	
	Doxazocin 6mg			C				Not Reported	

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Famotidine 40mg	C	Not Reported
Finasteride 5mg	C	Not Reported
Furosemide 40mg	C	Not Reported
Milk Of Magnesia 30ml	C	Not Reported
Rivaroxaban 20mg	C	Not Reported
Senna Tab 17.2mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797621	DIRECT	Y				62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797861	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxychloroquine Quetiapine			S C				Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797867	DIRECT	Y				86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Coronary Syndrome; Cerebrovascular Accident; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Respiratory Failure; Troponin Increased	Hydroxychloroquine			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797872	DIRECT	Y				84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Haemoglobin Decreased	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17797909	DIRECT	Y				82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	10614679	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1496772		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Cardiovascular Disorder; Condition Aggravated; Cystitis; Deformity; Depressed Mood; Dermatitis; Drug Ineffective; Encephalitis; Encephalitis Brain Stem; Fall; Fibromyalgia; Immobile; Immune System Disorder; Immunodeficiency; Insomnia; Joint Destruction; Loss Of Personal Independence In Daily Activities; Memory Impairment; Pain; Peripheral Swelling;	Actemra			S	Intravenous (not otherwise specified)	Started Summer 2013, Had 3 Doses In Total		Not Reported	
	Arava			S	Unknown			Not Reported	
	Celebrex			S	Unknown	2009 Or 2012 Start, Stopped Fall 2014. Later Re-Started It Again.		Not Reported	
	Celebrex			S	Unknown	Re-Started When Had A Rheumatoid Arthritis Flare		Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	6 Months		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine			S	Unknown	Stopped As Did Not Do		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Psychiatric Symptom; Rheumatoid Arthritis; Rheumatoid Arthritis; Rib Fracture; Scar; Seizure; Sepsis; Spinal Deformity; Vomiting	Sulfate] Plaquenil [Hydroxychloroquine Sulfate] Prednisone Prednisone Apo-Prednisone Dilaudid Dilaudid Lyrica Hydromorph Contin Hydromorph Contin Furosemide	S S S S C C C C C C	Unknown Unknown Unknown Oral Unknown Unknown Oral Unknown Unknown Unknown	Anything As Needed, Started 2009 Approximately As Required 2 Capsules Morning, 1 At Night, 2010 Start Approx. Sustained Release	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	15377600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184324		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Cough;	Actemra			S	Unknown	Therapy Duration: 365.0		Not Reported
Diarrhoea; Drug	Actemra			S	Oral			Not Reported
Ineffective; Dyspnoea; Eye	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 366.0		Not Reported
Haemorrhage; Gastric	Rituxan			S				Not Reported
Disorder; Gingival	Arava			S	Oral	Therapy Duration: 365.0		Not Reported
Bleeding; Headache;	Enbrel			S	Subcutaneous	Therapy Duration: 3 Months		Not Reported
Infection; Joint Swelling;	Humira			S	Subcutaneous	Therapy Duration: 366.0		Not Reported
Liver Function Test	Methotrexate			S	Unknown	Therapy Duration: 16.0 Years		Not Reported
Abnormal; Liver Function	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 638.0		Not Reported
Test Increased; Loss Of								
Personal Independence In								
Daily Activities; Off Label								
Use; Rash; Syncope;								
Urticaria								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 8.0 Years	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 396.0	Not Reported
Prednisone	C	Unknown		Not Reported
Prevacid	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	16743894	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR-APL-2019-056074			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Pregabalin 100 Mg Capsules, Hard			S	Unknown	1 Dosage Form, 3 Times A Day (1-1-1)		Not Reported	
	Pregabalin 100 Mg Capsules, Hard			S	Unknown	100 Milligram, 3 Times A Day (300 Milligram Once A Day)		Not Reported	
	Ramipril 2.5mg			S	Oral	1 Dosage Form, Two Times A Day		Aurobindo	
	Ramipril 2.5mg			S	Unknown	5 Milligram, Once A Day		Aurobindo	
	Sildenafil			S	Unknown	60 Milligram, Once A Day, Daily Dose		Aurobindo	
	Apixaban			S	Unknown	1 Dosage Form, Two Times A Day (1-0-1)		Not Reported	
	Apixaban			S	Unknown	2.5 Milligram, Two Times A Day (5 Milligram Once A Day)		Not Reported	
	Omeprazole			S	Oral	1 Dosage Form, Two Times A Day		Not Reported	
	Omeprazole			S	Oral	40 Milligram, Once A Day		Not Reported	
	Quensyl			S	Unknown	20 Milligram, Two Times A Day (40 Milligram, Once A		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			Day)	
Quensyl	S	Unknown	2 Dosage Form, Once A Day (1 Df, Bid)	Not Reported
Quensyl	S	Unknown	40 Milligram, Two Times A Day (80 Milligram Once A Day)	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Roactemra	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Spasmolyt	S	Unknown	1 Dosage Form, Once A Day (15, Qd ((1-0-0)))	Not Reported
Spasmolyt	S	Unknown	30 Milligram, Once A Day	Not Reported
Spasmolyt	S		30 Milligram, Once A Day, Number Of Separate Dosages: 1 Number Of Units In The Interval: 1	Not Reported
Tocilizumab	S	Subcutaneous	162 Milligram, Every Week	Not Reported
Volibris	S	Oral	30 Milligram, Once A Day	Not Reported
Volibris	S	Oral	1 Dosage Form, Once A Day	Not Reported
Volibris	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Lyrica	S	Unknown	100 Milligram, 3 Times A Day	Not Reported
Lyrica	S	Unknown	1 Dosage Form, 3 Times A Day (1 Df, 3x/Day (1 - 1-1))	Not Reported
Ambrisentan	S	Unknown	Unk	Not Reported
Ambrisentan	S	Oral	1 Dosage Form, Once A Day	Not Reported
Ambrisentan	S	Unknown	30 Milligram, Once A Day	Not Reported
Ambrisentan	S	Unknown	30 Milligram, Once A Day	Not Reported
Eliquis	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omeprazole	C	Unknown	40 Milligram, Once A Day (20 Milligram, Bid)	Not Reported
Quensyl	C	Unknown	40 Milligram, Once A Day (20 Mg Bid)	Not Reported
Ramipril	C	Unknown	5 Milligram, Once A Day (2.5 Mg, Bid)	Not Reported
Spasmolyt	C	Unknown	15 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17019442	EXPEDITED (15-DAY)		OT	CA-ROCHE-2457981		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Bronchitis; C- Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gait Inability; Glaucoma; Hepatic Enzyme Increased; Hypersensitivity; Hypertension; Insomnia; Limb Discomfort; Liver Disorder; Localised Infection; Musculoskeletal Discomfort; Off Label Use; Pain In Extremity; Pneumonia; Skin Reaction; Synovitis; Therapeutic Product Effect Decreased; Thyroid Disorder; Treatment Failure; Vomiting	Actemra Apo-Leflunomide Arava Cimzia Enbrel Hydroxychloroquine Methotrexate Orencia Sulfasalazine Azathioprine Hydroxychloroquine Sulfate Leflunomide Plaquenil [Hydroxychloroquine Sulfate] Sodium Aurothiomalate Dorzolamide Hydrochloride;Timolol Maleate Ergocalciferol Estradiol			S S S S S S S S S S S S S S C C C	Endocervical Unknown Unknown Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Estrogel	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Potassium Chloride	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Xalatan	C	Unknown	Not Reported
Zingiber Officinale	C	Unknown	Not Reported
Aspirin [Acetylsalicylic Acid]	C		Not Reported
Calcium	C		Not Reported
Ergocalciferol	C		Not Reported
Tiaprofenic Acid	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17526171	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020- 07695		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Erythema; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Off Label	Infliximab			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Codeine			S	Unknown	Unknown		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Use; Panniculitis;	Humira	S	Subcutaneous		Not Reported
Peripheral Swelling;	Humira	S	Subcutaneous		Not Reported
Product Use Issue; Rash;	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Rash Pruritic; Rheumatoid	Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Arthritis; Rheumatoid	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Nodule; Skin Necrosis;	Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Skin Ulcer	Leflunomide	S	Unknown	Unknown	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Myochrysine	S	Intramuscular	Solution Intramuscular	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown	Unknown	Not Reported
	Sulfasalazine	S			Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Prednisone	C	Unknown	Unknown	Not Reported
	Xeljanz	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17687239	EXPEDITED (15-DAY)		DE, LT	FR-SUN PHARMACEUTICAL		80 YR	Female	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

INDUSTRIES LTD-
2020RR-244297

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	()		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	()		Not Reported
	Perfalgan 10 Mg/Ml, Solution Pour Perfusion			C	Intravenous (not otherwise specified)	()		Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)	()		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	()		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Daily		Not Reported
	Transipeg			C	Oral	()		Not Reported
	Potassium (Chlorure De)			C	Intravenous (not otherwise specified)	()		Not Reported
	Effexor L.P. 37,5 Mg, Gelule A Liberation Prolongee			C	Oral	Unk		Not Reported
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk		Not Reported
	Seresta 10 Mg, Comprime			C	Oral			Not Reported
	Rocephine			C	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17703365	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-019744		71 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Overdose; Oxygen Saturation Decreased; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Paracetamol Paracetamol Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Lovenox Lovenox Dexamethasone Movicol Movicol Lasilix Pantoprazole Pantoprazole Lantus Tienam	S S S S S S S S S S S S C C C C C C C	Other Unknown Other Unknown Other Other Other Other Other Subcutaneous Subcutaneous Intravenous (not otherwise specified) Other Parenteral Oral Subcutaneous Intravenous (not otherwise specified)	4 Gram, Once A Day 800 Milligram, Once A Day 1200 Milligram, Once A Day 400 Milligram, Once A Day 400 Milligram, Once A Day 400 Milligram, Once A Day 600 Milligram, Once A Day 1000 Milligram, Once A Day 400 Milligram, Once A Day 0.6 Milliliter, Once A Day 0.7 Milliliter, Once A Day 20 Milligram, Once A Day 2 Dosage Form, Once A Day 40 Milligram, Once A Day 40 Milligram, Once A Day 20 International Unit, Once A Day 1 Gram, 3 Times A Day	Aurobindo Aurobindo Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17727385	EXPEDITED (15-DAY)		DE, HO, OT	SK-ACCORD-180080		57 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Bulbar Palsy; Cardiac Arrest; Cerebral	Methotrexate			S		Unk		Accord	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infarction; Dizziness;	Mycophenolic Acid	S			Accord
Hypotension; Intentional	Azathioprine/Azathioprine	S	Unk		Not Reported
Product Use Issue; Jc	Sodium				
Virus Infection; Mental	Belimumab	S	Unk		Not Reported
Impairment; Pneumonia;	Cyclophosphamide/Cyclophosph	S	Unk		Not Reported
Progressive Multifocal	amide Monohydrate				
Leukoencephalopathy;	Ciclosporin	S	Unk		Not Reported
Respiratory Failure;	Hydroxychloroquine	S	Unk		Not Reported
Speech Disorder; Tremor	Prednisone	S	Unk		Not Reported
	Mycophenolate Mofetil	S	Unk		Not Reported
	Prednisone	S	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17764120	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-246394		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Long Qt Syndrome;	Azithromycin			S	Oral	500 Milligram, Daily		Sun
Sudden Death	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Milligram, 1dose/6hour		Not Reported
	Dolquine 200 Mg Comprimidos			S	Oral	400 Milligram, Bid		Not Reported
	Recubiertos, 30 Comprimidos			S				Not Reported
	Dolquine 200 Mg Comprimidos			S	Intravenous (not otherwise specified)	10 Milligram, Tid		Not Reported
	Recubiertos, 30 Comprimidos			S	Intravenous (not otherwise specified)	()		Not Reported
	Metoclopramida (1958a)			S				Not Reported
	Propofol (2373a)			S				Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Microgram, 1dose/6hour		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	Unk		Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4 Gram, Bid		Not Reported
	Midazolam (2256a)			C	Intravenous drip	100 Milligram, Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tocilizumab (8289a)	C	Intravenous (not otherwise specified)	600 Milligram, Daily	Not Reported
Tocilizumab (8289a)	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17791594	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050907			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm	
	Azithromycin			S				Zydus Pharm	
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram Every 8 Hours		Not Reported	
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported	
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab Paracetamol			S S	Oral	1 Gram Every 8 Hours		Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17791595	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050817			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm	
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported	
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S				Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Lopinavir/Ritonavir	S	Oral	2u Cada 12h	Not Reported
Lopinavir/Ritonavir	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17791596	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050851			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Single		Not Reported
	Kaletra			S	Oral	2u Cada 12h		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Mg Dia		Not Reported
	Dolquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17791597	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050909			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Hidroxiclороquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Hidroxiclороquina [Hydroxychloroquine Sulfate]			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17791598	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050908			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Zydus Pharm
	Azithromycin			S				Zydus Pharm
	Hidroxicloroquina [Hydroxychloroquine Sulfate]			S	Oral	400 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 Gram Every 6 Hours		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794272	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES- 1234955		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Day		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794307	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES- 1234956		71 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva

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	Hidroxiclороquina (2143a)	S							Teva
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg					Not Reported
	Tocilizumab (8289a)	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794360	EXPEDITED (15-DAY)		HO, LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247339		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Metilprednisolona (888a)			S	Intravenous (not otherwise specified)	250 Milligrams, Daily		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Compri...			S	Oral	2 Dosage Form, Bid		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram, Daily		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	200 Milligram, Bid		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	560 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794364	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247343		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Mg Dia		Sun
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	In Total		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Compri...			S	Oral	2u Cada 12h		Not Reported

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Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794502	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050853			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hyponatraemia	Levofloxacin			S	Oral	500 Mg		Zydus Pharm	
	Dolquine			S	Oral	400 Mg		Not Reported	
	Kaletra			S	Oral	2 Dosage Form		Not Reported	
	Kaletra			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794877	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1234795		43 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Mg		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795605	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050808			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg		Zydus Pharm	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	

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	Tocilizumab	S						Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S	Oral	400 Mg				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795606	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050813			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg		Zydus Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Ceftriaxona [Ceftriaxone]			S				Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795681	EXPEDITED (15-DAY)		DS, OT	CA-SAMSUNG BIOEPIS-SB-2020- 15879		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; C- Reactive Protein Increased; Condition Aggravated;	Etanercept			S	Unknown	Unknown		Not Reported
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling;	Adalimumab			S	Subcutaneous	Unknown		Not Reported
Musculoskeletal Pain;	Abatacept			S	Unknown	Unknown		Not Reported
Pain In Extremity;	Arava			S	Unknown			Not Reported
Peripheral Swelling; Rash;	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Ascorbic Acid			S	Unknown	Unknown		Not Reported
	Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Co Atenolol			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported

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Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Ferrous Fumarate	S	Unknown	Unknown	Not Reported
	Ferrous Fumarate W/Folic Acid	S	Unknown	Unknown	Not Reported
	Ferrous Fumarate W/Folic Acid	S	Unknown	Unknown	Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Naprosyn [Naproxen]	S	Oral		Not Reported
	Naprosyn [Naproxen]	S	Oral		Not Reported
	Naprosyn [Naproxen]	S	Oral		Not Reported
	Naproxen	S	Oral		Not Reported
	Naproxen	S	Oral		Not Reported
	Naproxen	S	Oral		Not Reported
	Naproxen	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Naproxen Sodium	S	Oral		Not Reported

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Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Palafer	S	Unknown	Unknown	Not Reported
Palafer Cf	S	Unknown	Unknown	Not Reported
Pantoloc	S	Unknown		Not Reported
Pantoloc	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Unknown	Unknown	Not Reported
Sulfasalazine	S	Oral		Not Reported
Celebrex	C	Oral		Not Reported
Celecoxib	C	Unknown	Unknown	Not Reported
Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795759	EXPEDITED (15-DAY)		OT	GB-ACCORD-181478		41 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Febrile Convulsion; Generalised Tonic-Clonic Seizure	Hydroxychloroquine			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795794	EXPEDITED (15-DAY)		OT	NVSC2020GB130263		23 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis; Immune Thrombocytopenia; Liver Function Test Abnormal; Pleurisy; Systemic Lupus Erythematosus	Azathioprine			S	Unknown	150 Mg		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Novartis	
	Prednisolone			S	Unknown	7.5 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795850	EXPEDITED (15-DAY)		OT	ES-ACCORD-182145		43 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Paracetamol			S	Oral	1gr Every 8 Hours		Accord	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795851	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-180063		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Off Label Use; Sudden Death	Tacrolimus			S	Oral			Accord	
	Levofloxacin/Levofloxacin Mesylate			S	Unknown			Not Reported	
	Lopinavir/Ritonavir			S	Oral			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Ceftriaxone/Ceftriaxone Sodium			C	Unknown			Not Reported	
	Enoxaparin			C	Subcutaneous			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795856	EXPEDITED (15-DAY)		OT	SI-ACCORD-182063		50 YR	Male	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Disorder; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg 15.4. In The Evening And 16.4 In The Morning 400 Mg, Then 200 Mg/12 H		Not Reported
	Daleron			S	Oral	500 Mg; As Necessary, Dotal Dose Of 2 Tbl On 14. And 15.4.		Not Reported
	Fragmin			S	Subcutaneous	5000, 5000/24 Ur		Not Reported
	Pantoprazol Teva			C	Oral	20 Mg; 20 Mg/Day		Not Reported
	Folkodin Alkaloid-Int			C	Oral	10 Mg; As Necessary 2caps/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597666		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis;	Rituximab			S	Intravenous drip			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Every 1 Days	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Risedronate	S	Unknown		Not Reported
	Risedronate	S	Unknown		Not Reported
	Risedronate Sodium	S	Oral		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795927	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050898			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Levofloxacin			S	Unknown	Unk		Zydus Pharm
	Azithromycin			S	Oral	500 Milligram		Zydus Pharm
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram		Not Reported
	Prednisona			C	Oral			Not Reported
	Enoxaparina Sodica			C	Subcutaneous			Not Reported
	Ceftriaxona [Ceftriaxone]			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17795960	EXPEDITED (15-DAY)		DE, OT	FR-MALLINCKRODT-T202002262		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronavirus Infection; Diarrhoea; Hepatocellular Injury	Ofirmev			S	Intravenous (not otherwise specified)	4 Gram, Qd		Mallinckrodt	
	Linezolid Kabi			S	Intravenous (not otherwise specified)	1200 Milligram, Qd		Not Reported	
	Rovamycine			S	Intravenous (not otherwise specified)	4.5 Mega-International Unit, Qd		Not Reported	
	Plaquenil			S	Oral	600 Milligram, Qd		Not Reported	
	Cefotaxime			S	Intravenous (not otherwise specified)	6 Gram, Qd		Not Reported	
	Movicol Plain			C	Unknown	Unk		Not Reported	
	Amikacine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17629401	NON-EXPEDITED			US-AMGEN-USASP2020048450		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Enbrel			S	Unknown	Unk		Amgen	
	Remicade			S	Intravenous (not otherwise specified)	3 Mg/Kg, 0, 2, 6 Wks, Then Every 8 Wks		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 8 Weeks		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 7 Weeks		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	

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Otrexup	S	Unknown	Unk	Not Reported
Otrexup	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17691077	EXPEDITED (15-DAY)		HO	CA-ROCHE-2584754			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Product Label Confusion; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulphate			S	Oral			Not Reported
	Cimzia			C	Subcutaneous			Not Reported
	Enbrel			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17796047	EXPEDITED (15-DAY)		HO, LT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-050911			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Qd		Zydus Pharm
	Methylprednisolone			S	Intravenous (not otherwise specified)	250 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Kaletra	S	Oral	2 Dosage Form	Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 Gram	Not Reported
Dolquine	S	Oral	200 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	560 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17796048	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050934			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Zydus Pharm
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported
	Dolquine			S	Oral	200 Milligram		Not Reported
	Midazolam			S	Unknown			Not Reported
	Midazolam			S				Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Unknown	Unk		Not Reported
	Omnice Ocas			C	Unknown			Not Reported
	Simvastatina			C	Unknown			Not Reported
	Cortica			C	Unknown	Corticoides A Dosis Bajas		Not Reported
	Kalpress			C	Unknown	Unk		Not Reported
	Manidon Hta			C	Unknown	Unk		Not Reported
	Rilast			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17796097	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-02		75 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort	Combivent			S	Unknown	Form Of Admin: Solution Inhalation		Boehringer Ingelheim
	Alendronate Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Lasix [Furosemide]			S	Unknown			Not Reported
	Lipitor [Atorvastatin]			S	Unknown			Not Reported
	Losec [Omeprazole]			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Nitrazadon			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salmeterol Xinafoate			S	Unknown			Not Reported
	Tylenol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17796109	EXPEDITED (15-DAY)		DE, OT	BE-ADVANSZ PHARMA- 202004005128			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Kevzara			S	Unknown	Unk		Not Reported
	Kevzara			S				Not Reported
	Sarilumab Autoinjector			S	Unknown	Unk		Not Reported
	Sarilumab Autoinjector			S				Not Reported
	Azithromycin			C		Unk		Not Reported
	Cefuroxime			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2020	17796127	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1235371			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosis	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	11042903	EXPEDITED (15-DAY)		OT	CA-ROCHE-1565162		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Tenderness; Arthralgia; Arthralgia; Arthropathy; Drug Ineffective; Drug Ineffective; Fatigue; Groin Pain; Joint Injury; Joint Range Of Motion	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 990.0 Nos		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Pain; Pain In Extremity; Pain In Extremity; Peripheral Swelling; Retinal Toxicity; Rheumatoid Arthritis; Sleep Disorder; Swelling; Swelling	Methotrexate Plaquenil [Hydroxychloroquine Sulfate] Plaquenil [Hydroxychloroquine Sulfate] Apo-Leflunomide Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Xeljanz Tramadol Hcl Rabeprazole Sodium	S S S S S S C C C	Unknown Unknown Unknown Unknown Unknown Oral Oral Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	12905295	EXPEDITED (15-DAY)		OT	CA-ROCHE-1624144		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Vioxx			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Wellbutrin	C		Not Reported
Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	12974330	EXPEDITED (15-DAY)		OT	CA-ROCHE-1858733			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Drug Ineffective; Ill-Defined Disorder; Osteoarthritis; Red Blood Cell Sedimentation Rate Increased; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	13011431	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865032		75 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Abatacept			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 486.0 Nos		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Minocycline			C	Unknown			Not Reported
	Penicillamine			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported
	D-Penicillamine			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	13045102	EXPEDITED (15-DAY)		OT	CA-ROCHE-1869641		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bedridden; Crying; Drug Ineffective	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Folinic Acid			C	Unknown			Not Reported
	Apo-Hydroxyquine			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Calcium			C	Unknown			Not Reported
	Leucovorin [Folinic Acid]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	13132261	EXPEDITED (15-DAY)		OT	CA-ROCHE-1619414		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Drug Intolerance; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 987 Days		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased	Cimzia	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Lyrica	S	Oral		Not Reported
	Xeljanz	S	Oral	Therapy Duration: 2 Years	Not Reported
	Xeljanz	S	Oral	Therapy Duration: 3 Months	Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Prednisone	C	Oral		Not Reported
	Arava	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	13316486	EXPEDITED (15-DAY)		OT	CA-ROCHE-1808908			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Colitis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Incomplete; Treatment
Failure; White Blood Cell
Count Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	13663116	EXPEDITED (15-DAY)		OT	CA-ROCHE-1951182		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Treatment Failure; Tremor	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	Therapy Duration: 9 Months		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
	Pantoprazole Magnesium			C	Unknown			Not Reported	
	Tenofovir Disoproxil			C	Unknown			Not Reported	
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Zopiclone			C	Unknown			Not Reported	
	Methotrexate			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tenofovir

C

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	14058071	EXPEDITED (15-DAY)		OT	CA-SA-2017SA182819		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Somnolence; Visual Impairment	Plaquenil			S	Oral	200 Mg,Bid		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Hydroxychloroquine Sulfate			S		200 Mg, Bid		Sanofi
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Leflunomide			S		20 Mg, Qd		Sanofi
	Paracetamol			S	Unknown	Unk Unk,Prn		Not Reported
	Paracetamol			S				Not Reported
	Paracetamol			S		325 Mg		Not Reported
	Sulfasalazine			S	Oral	2000 Mg,Unk		Not Reported
	Acetaminophen;Diphenhydramine Hydrochloride			S				Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S		Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Tylenol			C				Not Reported
	Codeine Phosphate			C	Unknown	Unk Unk,Unk		Not Reported
	Leflunomide			C	Unknown	20 Mg, Qd		Not Reported
	Celebrex			C	Oral	200 Mg,Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorphone Hcl	C			Not Reported
Acetaminophen;Codeine Phosphate	C			Not Reported
Hydromorph	C	Unknown	Unk Unk,Prn	Not Reported
Methotrexate	C	Unknown	25 Mg,Qw	Not Reported
Synthroid	C		Unk Unk,Unk	Not Reported
Meloxicam	C		Unk Unk,Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	14165914	EXPEDITED (15-DAY)		OT	CA-SA-2017SA210506		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Arava			S	Oral	20 Mg,Qd		Sanofi
	Paracetamol			S	Unknown	Unk Unk,Unk		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Plaquenil			S	Unknown	200 Mg,Bid		Sanofi
	Paracetamol			S		325 Mg		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	50 Mg,Qw		Not Reported
	Humira			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Meloxicam			C	Unknown			Not Reported
	Methotrexate			C	Unknown	25 Mg/MI, Qw		Not Reported
	Acetaminophen And Codeine Phosphate			C	Unknown	Unk, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Synthroid	C	Unk Unk,Unk	Not Reported
Tylenol [Paracetamol]	C		Not Reported
Leflunomide	C	Unknown 20 Mg, Qd	Not Reported
Celebrex	C		Not Reported
Hydromorphone Hcl	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	15100628	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0716		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Apo-Azathioprine			S	Vaginal			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Imuran			S	Unknown			Not Reported
	Methotrexate Sodium			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Cimzia			S				Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S				Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C		Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	15394598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184764		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arthrotec			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Imuran [Azathioprine]			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	15755439	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-2229884			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
Azathioprine			C	Unknown			Not Reported	
Imuran [Azathioprine]			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	16005011	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA139124		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S				Sanofi
	Sodium Aurothiomalate			S	Unknown	Unk Unk,Unk		Not Reported
	Actemra			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S	Unknown	Unk Unk,Unk		Not Reported
	Kineret			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Cellcept [Mycophenolate Mofetil]			S	Unknown	Unk Unk,Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
	Gold			S	Unknown			Not Reported
	Celebrex			C	Unknown	Unk Unk,Unk		Not Reported
	Methotrexate			C	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			C	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Humira			C	Subcutaneous	Unk Unk,Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	16095354	EXPEDITED (15-DAY)		OT	CA-BECTON		45 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

DICKINSON-
2019BDN00113

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Chloraprep			S	Topical			Becton Dickinson
	Chlorhexidine			S				Becton Dickinson
	Chlorhexidine Gluconate			S				Becton Dickinson
	Abatacept			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S				Not Reported
	Acetaminophen/Oxycodone			S				Not Reported
	Hydrochloride							
	Acetaminophen/Oxycodone			S				Not Reported
	Hydrochloride/Oxycodone							
	Terephthalate							
	Act Oxycodone Cr			S				Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, 1x/Month		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month		Not Reported
	Actemra			S		Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg; 4 Every 1 Week		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728.0 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, Unk		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	752.8 Mg, 1 Every 4 Week(S)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	728 Mg, 1 Every 4 Week(S)		Not Reported
	Actemra			S	Intravenous (not	728.0 Mg, 1x/Month		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Actemra	S	Intravenous (not otherwise specified)	752.8 Mg, 1x/Month	Not Reported
Actemra	S	Intravenous (not otherwise specified)	725 Mg, Every 4 Weeks	Not Reported
Apo-Acetaminophen	S			Not Reported
Chlorhexidine Gluconate Oral Rinse	S			Not Reported
Cimzia	S	Subcutaneous		Not Reported
Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S		Unk	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Leflunomide	S			Not Reported
Methotrexate	S			Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate Sodium	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Oxycodone	S			Not Reported
Oxycodone-Acetaminophen	S			Not Reported
Oxycodone Cr	S			Not Reported
Oxycodone Hydrochloride	S			Not Reported
Oxycodone Terephthalate	S			Not Reported
Periogard	S			Not Reported
Periogard Alcohol Free	S	Buccal		Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Periarticular	Unk	Not Reported
Sulfamethoxazole	S			Not Reported
Sulfamethoxazole/Trimethoprim	S			Not Reported
Arava	C	Oral	20 Mg, 1x/Day	Not Reported
Arava	C		Unk	Not Reported
Cetirizine	C			Not Reported
Cetirizine Hydrochloride	C			Not Reported
Desogestrel/Ethinyl Estradiol	C			Not Reported

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Hydroxychloroquine Phosphate	C			Not Reported
Hydroxychloroquine Sulfate	C	400 Mg, 1x/Day		Not Reported
Ibuprofen	C			Not Reported
Pantoloc	C			Not Reported
Pantoprazole	C			Not Reported
Pantoprazole Sodium	C			Not Reported
Paracetamol	C			Not Reported
Paracetamol/Codeine	C			Not Reported
Plaquenil	C			Not Reported
Prednisone	C	Oral	7.5 Mg, 1x/Day	Not Reported
Prednisone	C		Unk	Not Reported
Reactine	C		10 Mg, 2x/Day	Not Reported
Reactine	C		Unk	Not Reported
Tylenol	C			Not Reported
Tylenol With Codeine	C			Not Reported
Tylenol #1	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	16438452	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019- 15073			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosis	Etanercept			S	Unknown	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Actemra			S	Unknown	Unknown		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unknown		Not Reported
	Arava			S	Unknown	Unknown		Not Reported
	Arava			S	Oral	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown, Solution		Not Reported

FDA Adverse Event Reporting System

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				Subcutaneous, Single-Use Pre-Filled Syringe	
Desoximetasone	S	Unknown	Unknown		Not Reported
Desoximetasone	S	Oral	Unknown		Not Reported
Folic Acid	S	Unknown	Unknown		Not Reported
Folic Acid	S				Not Reported
Fosamax	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Unknown	Unknown		Not Reported
Hydroxychloroquine	S	Oral	Unknown		Not Reported
Methotrexate	S	Unknown	Unknown		Not Reported
Methotrexate	S				Not Reported
Orencia	S	Subcutaneous	Unknown		Not Reported
Prednisone	S	Unknown	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown, Solution Intravenous		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Simponi	S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
Simponi	S	Subcutaneous	Unknown		Not Reported
Sulfasalazine	S	Unknown	Unknown		Not Reported
Enbrel	S	Unknown	Unknown		Not Reported
Enbrel	S				Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown		Not Reported
Cetirizine Hydrochloride	S	Unknown	Unknown		Not Reported
Cetirizine	S	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	16936539	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436270		63 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17063576	EXPEDITED (15-DAY)		HO	CA-ROCHE-2472424			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate] Remicade	S S	Oral Intravenous (not otherwise specified)	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17070136	EXPEDITED (15-DAY)		HO	CA-ROCHE-2474304			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate] Remicade			S S	Unknown Intravenous (not otherwise specified)	 Powder For Solution		Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17258667	EXPEDITED (15-DAY)		OT	CA-ROCHE-2513921		55 YR	Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Other			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17310605	EXPEDITED (15-DAY)		OT	CA-009507513-2001CAN007489		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthralgia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Hypersensitivity; Infusion Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During	Fosamax			S	Unknown	Unk		Merck
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution For Injection In Pre-Filled Pen		Merck
	Simponi			S	Subcutaneous	Unk		Merck
	Actemra			S	Subcutaneous	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Apo Prednisone			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Musculoskeletal Stiffness; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wound	Arava	S	Oral	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral		Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram	Not Reported
	Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	400 Milligram; Solution For Injection In Pre-Filled Syringe	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cortisone Acetate	S		25 Milligram	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	5.0 Milligram	Not Reported
	Folic Acid	S	Unknown	1 Milligram	Not Reported
	Golimumab	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	40 Milligram	Not Reported
	Humira	S	Subcutaneous	Formulation: Solution Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Oral	20.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Methotrexate	S	Oral	25 Milligram 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Intra-arterial	25 Milligram, 1 Every 1 Weeks	Not Reported
	Methotrexate	S	Unknown	20 Milligram, 1 Every 1 Days	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	400.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Plaquenil	S			Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Milligram	Not Reported
Prednisone	S	Oral	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfasalazine	S	Oral	1000.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Sulfasalazine	S	Unknown	500 Milligram	Not Reported
Sulfasalazine	S	Subcutaneous	1 Gram, 2 Every 1 Day	Not Reported
Sulfasalazine	S	Subcutaneous	500 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Diclofenac Sodium	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Apo Folic Acid	S	Unknown		Not Reported
Prednisone	S	Oral		Not Reported
Diclofenac	C	Unknown	50 Milligram	Not Reported
Diclofenac	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17721927	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202004003827			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Off Label Use; Septic Shock	Hydroxychloroquine			S	Oral	400 Mg, Qd, Film Coated Tablet		Concordia
	Enoxaparin			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Spiramycin			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Noradrenaline [Norepinephrine]			C		2.4 Mg/Hour		Not Reported
	Solumedrol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17723898	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020169257		51 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	1 Df, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Atrovent			C	Respiratory (inhalation)	3 Df, Daily		Not Reported
	Bricanyl			C		3 Df, Daily		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	Unk		Not Reported
	Coversyl [Perindopril Arginine]			C	Oral	1 Df, Daily		Not Reported
	Perfalgan			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17755163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592591		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaphylactic Reaction;	Actemra	S	Unknown		Not Reported
Arthralgia; Blood	Actemra	S	Unknown		Not Reported
Creatinine Increased;	Rituximab	S	Unknown		Not Reported
Contraindicated Product	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Administered; Drug	Rituximab	S	Unknown		Not Reported
Hypersensitivity; Drug	Rituximab	S	Unknown		Not Reported
Ineffective; Drug	Abatacept	S	Unknown	7.0 Months	Not Reported
Intolerance; Loss Of	Adalimumab	S	Unknown	9.0 Years	Not Reported
Personal Independence In	Ciclosporin	S	Unknown		Not Reported
Daily Activities; Mobility	Cyclosporine	S	Unknown		Not Reported
Decreased;	Enbrel	S	Unknown		Not Reported
Musculoskeletal Pain;	Humira	S	Subcutaneous		Not Reported
Neck Pain; Pain In	Hydroxychloroquine	S	Unknown		Not Reported
Extremity; Pain In Jaw;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rheumatoid Arthritis	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17763811	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593629			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive	Actemra			S	Unknown			Not Reported
Protein Increased; Drug	Hydroxychloroquine			S	Unknown			Not Reported
Hypersensitivity; Drug	Orencia			S	Unknown			Not Reported
Ineffective; Gait Inability;	Tramadol			S	Unknown			Not Reported
Joint Swelling; Mobility	Tramadol Hydrochloride			S	Unknown			Not Reported
Decreased; Off Label Use;	Enbrel			S	Unknown			Not Reported
Rheumatoid Arthritis;	Arava			C	Unknown			Not Reported
Treatment Failure								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira	C	Subcutaneous	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Methotrexate	C	Oral	Not Reported
	Methotrexate	C	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17790725	EXPEDITED (15-DAY)		DE, OT	IT-ABBVIE-20K-083-3402967-00		59 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gamma-Glutamyltransferase Increased; Hepatotoxicity; Hypertransaminasaemia; Off Label Use; Septic Shock	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796741	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123205			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Adverse Drug Reaction; Adverse Reaction; Arthropathy; Deafness;	Arava			S	Unknown	Unk		Sanofi	
	Acetylsalicylic Acid			S	Unknown			Not Reported	
	Diclofenac			S	Topical	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deafness Transitory; Decreased Appetite; Dizziness; Drug Hypersensitivity; Ear Infection; Feeding Disorder; Functional Gastrointestinal Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Headache; Hypophagia; Musculoskeletal Disorder; Nausea; Pharyngitis; Vomiting; Weight Decreased	Diclofenac Diclofenac Potassium Hydroxychloroquine Methotrexate Naproxen Hydroxychloroquine Sulfamethoxazole/Trimethoprim Diclofenac Enbrel Gold Gold Sodium Thiomalate Humira Tramadol Hydrochloride	S S S S S S S S S S S C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Subcutaneous	Unk Unk Unk 	Not Reported Not Reported Sanofi Not Reported Not Reported Sanofi Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796742	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123089			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Leflunomide Hydroxychloroquine Hydroxychloroquine Sulfate Methotrexate Methotrexate Sulfasalazine Rituximab Varenicline Tartrate Actemra Cimzia Enbrel			S S S S S S S S S S S	Unknown Unknown Unknown Subcutaneous Subcutaneous Unknown Intravenous (not otherwise specified) Oral Unknown Unknown Unknown	20 Mg 400 Mg 400 Mg 20 Mg, Qw 25 Mg, Qw Unk 1 Df, Qd Unk Unk Unk 50 Mg	 	Sanofi Sanofi Sanofi Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Esomeprazole Magnesium Trihydrate	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Oxycodone Hydrochloride	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Valtrex	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796745	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA123222			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Arava			S	Oral	20 Mg		Sanofi
Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash;	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 2 Every 1 Day		Sanofi
Therapeutic Product Effect Decreased; Weight Decreased	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Prednisone			S	Oral	5 Mg, 1 Every 1 Day		Not Reported
	Sulfasalazine			S		1000 G, 2 Every 1 Day		Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Humira			S		20 Mg, 1 Every 1 Day		Not Reported
	Orencia			S		Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2 Every 1 Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796746	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122659		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Contraindicated Product	Arava	S				Sanofi
Administered; Drug	Leflunomide	S				Sanofi
Ineffective; Drug	Leflunomide	S		Unk		Sanofi
Intolerance; Inappropriate Schedule Of Product Administration;	Hydroxychloroquine Sulfate	S		Unk		Sanofi
Inappropriate Schedule Of Product Administration;	Methotrexate	S		Unk		Not Reported
Liver Function Test	Actemra	S		Unk		Not Reported
Increased; Rash;	Cimzia	S		Unk		Not Reported
Rheumatoid Arthritis	Enbrel	S	Subcutaneous	50 Mg		Not Reported
	Humira	S		40 Mg		Not Reported
	Orencia	S		125 Mg, Qw		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1 G		Not Reported
	Simponi	C	Subcutaneous	50 Mg, Qm		Not Reported
	Prednisone	C		Unk		Not Reported
	Sulfasalazine	C		Unk		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796747	EXPEDITED (15-DAY)		OT	ES-SA-2020SA124226		62 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Hypocoagulable State;	Enoxaparin Sodium			S	Subcutaneous	80 Mg		Sanofi
Hypofibrinogenaemia;	Enoxaparin Sodium			S	Unknown	Unk		Sanofi
Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Roactemra			S	Intravenous (not	600 Mg		Not Reported

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796759	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122582			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Condition Aggravated; Drug Intolerance; Headache; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Vomiting	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Sanofi
	Enbrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Morphine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17796995	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600501			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; Drug Ineffective; Off Label Use; Weight Increased	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Levothyroxine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17797026	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596275			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Inflammation; Interstitial Lung Disease; Joint Swelling; Musculoskeletal Stiffness	Rituximab			S	Intravenous drip	Therapy Duration: 403.0 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 0.0		Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Adalimumab			S	Subcutaneous	Therapy Duration: 8.0 Years		Not Reported
	Imuran [Azathioprine]			S	Unknown	Therapy Duration: 21.0 Years		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 31.0		Not Reported
	Glyburide			C	Oral			Not Reported
	Infliximab			C	Unknown			Not Reported
	Lipitor [Atorvastatin Calcium]			C	Unknown			Not Reported
	Metformin			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17797182	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235401			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Acetaminophen			S	Unknown			Not Reported
	Propofol			S	Unknown			Actavis
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

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	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17797231	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600590		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17797302	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA- 202004004827			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Endotracheal Intubation; Mechanical Ventilation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycine			C		Unk		Not Reported

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18-May-2020	17797376	EXPEDITED (15-DAY)		OT	MX-ADVANZ PHARMA-202005005211			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia; Off Label Use	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia	
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17797559	EXPEDITED (15-DAY)		OT	NVSC2020PH132416		80 YR	Female	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication; Suspected Covid-19	Azithromycin			S	Oral	0.5 Df (250 Mg), Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17797999	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247406		45 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia	Azithromycin			S	Unknown	Unk		Sun	
	Kaletra			S	Unknown	Unk		Not Reported	
	Interferon Beta-1b (2305od)			S	Unknown	Unk		Not Reported	
	Ceftriaxona (501a)			S	Unknown	Unk		Not Reported	
	Hidroxycicloroquina (2143a)			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798034	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598836		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C		Not Reported
	Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798156	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1228873		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Long Qt Syndrome	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798212	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-014076		26 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy	Dexametasona			S	Intravenous (not otherwise specified)	20 Mg Dia		Bausch And Lomb
	Enoxaparina			S	Subcutaneous	40mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	Total Dose: 600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Dexketoprofeno			S	Intravenous (not otherwise specified)	25 Mg Every 8 Hours		Not Reported
	Hidroxiclороquina			S	Oral	400 Mg Dia		Not Reported
	Azitromicina			S	Oral	500 Mg Dia		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798226	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235250			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Erythematous; Wound	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798348	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503968			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Psoriatic Arthropathy	Otezla			S	Unknown			Celgene
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Remicade			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Stelara			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

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18-May-2020	17798480	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1235771		82 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Erythema	Darunavir			S	Oral	1 Dosage Forms		Teva
	Colchicina Lirca			S	Oral	1 Dosage Forms		Not Reported
	Plaquenil			S		2 Dosage Forms		Not Reported
	Ritonavir Sandoz			S	Oral	1 Dosage Forms		Not Reported
	Clexane			C				Not Reported
	Pradaxa 150mg Hard Capsules			C				Not Reported
	Lasix 25 Mg Compresse			C				Not Reported
	Bisoprolol Fumarate			C				Not Reported
	Zopranol			C	Oral			Not Reported
	Cordarone 200 Mg Compresse			C				Not Reported
	Omeprazole			C				Not Reported
	Enoxaparin Sodium			C	Subcutaneous	4000 Ku		Not Reported
	Symbicort, 160 Microgrammi/4,5 Microgrammi/ Inalazione, Polvere Per In			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798522	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1047718		83 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use	Trazodone			S		1/4 Tablet In The Morning And At Noon And 1/2 Tablet In The Evening		Not Reported
	Trazodone			S		Unk		Not Reported
	Plaquenil /00072603/			S	Oral	Day 1: 400mg 2x/D Day 2-4: 200mg 1x/D 7/04 : Received 2x 400 Mg 08/04 To 10/04		Mylan
	Zyprexa			S		Unk		Mylan

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Zyprexa	S		1/2 Tablet 2x/Day Treatment Was Suspended For 2 Days 11/04 And 12/04 And Then Resumed	Mylan
Algostase Mono	C		1 Df, Tid	Mylan
Contramal	C		Unk Unk, Prn	Mylan
Pradaxa	C		Unk	Mylan
Movicol /01749801/	C		1 Df, Qd	Mylan
Uni Diamicron	C		60 Mg, Bid	Mylan
L-Thyroxine /00068001/	C		150 Ug, Qd	Mylan
Metformin	C		500 Mg, Bid	Mylan
Magnetop /00434501/	C	Oral	450 Mg, Qd	Mylan
Clexane	C		Unk	Mylan
Perindopril	C		2 Mg, Qd	Mylan
Kalium /00031401/	C		600 Mg	Mylan
Prolopa	C		0.5 Df, Qd	Mylan

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18-May-2020	17798528	EXPEDITED (15-DAY)	HO		FR-NATCO PHARMA- 2020NAT00018		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiotoxicity; Musculoskeletal Toxicity	Chloroquine Phosphate			S	Unknown	200 Mg, 1x/Day		Natco Pharma	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Acetylsalicylic Acid			C	Unknown	75 Mg, 1x/Day		Not Reported	
	Clopidogrel			C	Unknown	75 Mg, 1x/Day		Not Reported	
	Fenofibrate			C	Unknown	100 Mg, 1x/Day		Not Reported	
	Ranitidine			C	Unknown	300 Mg, 1x/Day		Not Reported	
	Clobetasol			S	Unknown	1 Application/Day		Not Reported	
	Paracetamol/Tramadol			C	Unknown	If Necessary		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798599	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235508		48 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypofibrinogenaemia; Pulmonary Embolism	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Azitromicina (7019a)			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798648	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123042		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Drug Intolerance; Headache; Migraine; Off Label Use; Product Use Issue; Respiratory Tract Infection; Therapeutic Product Effect Incomplete; Urinary Tract Infection; White Blood Cell Count Decreased	Arava			S	Unknown	20 Mg, Qd		Sanofi	
	Arava			S	Unknown	10 Mg, Qd		Sanofi	
	Arava			S	Unknown	10 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qod		Sanofi	
	Methotrexate			S	Oral	Unk		Not Reported	
	Methotrexate			S	Subcutaneous	Unk		Not Reported	
	Anakinra			S		Unk		Not Reported	
	Meloxicam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798652	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122868		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Hydroxychloroquine			S	Subcutaneous	Unk		Sanofi	
	Methotrexate			S	Oral	20 Mg		Not Reported	
	Sulfasalazine			S	Oral	Unk		Not Reported	

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Leflunomide	S		Unk	Sanofi
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Neoral	S	Subcutaneous	Unk	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Remicade	S		3 Mg	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798666	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1047766		49 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use; Rash; Rash Maculo-Papular	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Not Reported	
	Lopinavir/Ritonavir			S	Oral	4 Dosage Form, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798669	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1047777		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Long Qt Syndrome	Azithromycin			S	Unknown	No Especificada		Not Reported	
	Propofol			S	Unknown	Unk		Mylan	
	Propofol			S				Mylan	
	Dolquine			S	Oral	Un Comprimido Desayuno Y Cena		Mylan	
	Midazolam			S	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Midazolam	S							Mylan
	Kaletra	S	Oral		Unk				Mylan
	Ceftriaxona /00672201/	S	Unknown		No Especificada				Mylan
	Manidon Hta	C			Unk				Mylan
	Rilast	C			Unk				Mylan
	Omniv Ocas	C			Unk				Mylan
	Simvastatina	C			Unk				Mylan
	Kalpress	C			Unk				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798804	EXPEDITED (15-DAY)		OT	CA-SA-2020SA123322			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Lower Respiratory Tract Infection; Neck Pain; Pain In Extremity; Peripheral Swelling	Arava			S	Unknown	20 Mg, Qd		Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown	300 Mg, Qd		Sanofi	
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported	
	Sulfasalazine			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798828	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1047791		58 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate Aminotransferase; Hypertransaminasaemia; Off Label Use	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	1 Dosage Form, Qd		Not Reported	
	Kaletra			S	Oral	4 Dosage Form, Qd		Mylan	
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798848	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235389		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling; Therapeutic Product Effect Incomplete; Treatment Failure	Prednisone Methotrexate Methotrexate Mycophenolate Mofetil Piroxicam Pregabalin Actemra Arava Enbrel Gold Humira Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Orencia Remicade Rituximab/Vorhyaluronidase Alfa Simponi Sodium Aurothiomalate Sulfasalazine	S S S S S S S S S S S S S S S S S S S	Unknown Unknown Unknown Unknown Unknown Oral Subcutaneous Oral Unknown Unknown Unknown Unknown Oral Unknown Intravenous (not otherwise specified) Subcutaneous Subcutaneous Parenteral Unknown	Actavis Barr Barr Teva Not Reported Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798851	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1235527		72 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Hidroxicloroquina (2143a) Linezolid (1279a) Piperacilina Tazobactam 4g/0,5g			S S S	Oral Intravenous (not otherwise specified) Intravenous (not otherwise specified)	400 Mg Day 1200 Milligram Daily; 1 Dosage Form, C/8h		Teva Teva Not Reported

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	Roactemra 20 Mg/ML, Concentrado Para Solucion Para Perfusion	S		600mg		Not Reported
	Roactemra 20 Mg/ML, Concentrado Para Solucion Para Perfusion	S				Not Reported
	Meropenem (7155a)	S	Intravenous (not otherwise specified)	3 Gram Daily;		Not Reported
	Metamizol (111a)	S	Intravenous (not otherwise specified)	6 Gram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235812		34 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Exposure Before Pregnancy; Maternal Exposure During Pregnancy; Placental Insufficiency; Premature Delivery	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Unknown			Actavis	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798978	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235384		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Musculoskeletal Stiffness; Pain; Pulmonary Fibrosis	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799003	EXPEDITED (15-DAY)		OT	ES-ALLERGAN-2019800US			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Fosfomycin Tromethamine - Bp			S	Oral	3 G, Qd		Allergan	
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported	
	Azitromicina			S				Not Reported	
	Cefixima			S	Oral	400 Mg, Qd		Not Reported	
	Hidroxiclороquina			S	Oral	400 Mg, Qd		Not Reported	
	Hidroxiclороquina			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799007	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235779		48 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Paracetamol (12a)			S	Oral	3 Gram Daily; 1gr Every 8 Hours		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Mg Day		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Cefditoreno Pivoxilo (7358ps)			S	Oral	800 Milligram Daily; 400 Mg Every 12 Hours		Not Reported	
	Cefditoreno Pivoxilo (7358ps)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799090	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1235781		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	

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Dexametasona (722a)	S	Intravenous (not otherwise specified)	20 Mg	Not Reported
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;	Not Reported
Enoxaparina (2482a)	S	Subcutaneous	80 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799099	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235652		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Prednisone			S	Unknown			Actavis
Alopecia; Arthralgia;	Prednisone			S	Unknown			Actavis
Contraindicated Product	Prednisone			S	Unknown			Actavis
Administered; Drug	Alendronate Sodium			S	Unknown			Actavis
Ineffective;	Methotrexate			S	Subcutaneous			Barr
Hypersensitivity; Joint	Actemra			S	Unknown			Not Reported
Swelling; Maternal	Arava			S	Unknown			Not Reported
Exposure During	Cetirizine Hydrochloride			S	Unknown			Not Reported
Pregnancy;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Cetirizine Hydrochloride/Pseudoephedrine			S	Unknown			Not Reported
Pain; Pemphigus;	Hydrochloride							
Pericarditis; Product Use	Cimzia			S	Subcutaneous			Not Reported
Issue; Rheumatoid	Cortisone Acetate			S	Unknown			Not Reported
Arthritis; Systemic Lupus	Desoximetasone			S	Oral			Not Reported
Erythematousus;	Enbrel			S	Subcutaneous			Not Reported
Therapeutic Product Effect	Folic Acid			S	Unknown			Not Reported
Decreased; Treatment	Folic Acid			S	Unknown			Not Reported
Failure	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Methotrexate	S	Oral	20 Milligram Daily;	Not Reported
Methotrexate	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil	S	Unknown	400 Milligram Daily;	Not Reported
Plaquenil	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799108	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235526		48 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Colchicina (142a)			S	Oral	1 U Breakfast		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799283	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235458		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain; Peripheral Swelling	Prednisone			S	Oral	5 Milligram Daily;		Actavis
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Arava			S	Unknown	20 Milligram Daily;		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	20 Milligram Daily;		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	2000 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799351	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1235378		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness;	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Prednisone			S	Unknown	20 Milligram Daily;		Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Nasopharyngitis;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Oropharyngeal Pain; Pain;	Remicade	S	Unknown	Not Reported
Productive Cough;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Secretion Discharge;	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Sputum Discoloured;	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Thrombosis	Sulfasalazine	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799352	EXPEDITED (15-DAY)		OT	RO-MYLANLABS-2020M1002236		66 YR	Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia; Product Use In Unapproved Indication	Methotrexate			S	Unknown	Unk		Not Reported	
	Methotrexate			S				Not Reported	
	Hydroxychloroquine Sulfate			S		Unk		Mylan	
	Azathioprine			S	Unknown	Unk		Mylan	
	Hydroxychloroquine			S	Unknown	Unk		Mylan	
	Hydroxychloroquine			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799392	EXPEDITED (15-DAY)		OT	ES-BIODELIVERY SCIENCES INTERNATIONAL-2020BDSI0343		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Tinnitus	Fentanyl Citrate			S	Unknown			Not Reported	
	Azithromycin			S	Intravenous (not			Not Reported	

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Ceftriaxone	S	otherwise specified)	Intravenous (not otherwise specified)	Not Reported
Ritonavir/Lopinavir	S	Oral	(5 MI/12h)	Not Reported
Midazolam	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	200mg/12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799618	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1048632		60 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hidroxicloroquina /00072601/			S				Mylan
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg		Mylan
	Roactemra			C				Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	2 Gr Dia		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799620	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1048589		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, Total		Mylan
	Kaletra			S	Oral	2 Dosage Form, Bid		Mylan
	Kaletra			S				Mylan
	Dolquine			S	Oral	400 Milligram, Qd		Mylan
	Dolquine			S				Mylan

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799624	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1048642		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, (500 Mg Dia)		Not Reported	
	Lopinavir/Ritonavir			S	Oral	Unk, Bid, (2u Cada 12h)		Not Reported	
	Lopinavir/Ritonavir			S				Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Mylan	
	Roactemra			S				Mylan	
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan	
	Hidroxicloroquina /00072601/			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799987	EXPEDITED (15-DAY)		HO, OT	ES-ABBVIE-20K-144-3400696-00		11 YR	Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Off Label Use; Shock	Lopinavir/Ritonavir			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801751	DIRECT	Y	LT			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine Sulfate			S	Oral	Other Frequency:Bid X1day,Then Qd;		Sandoz	
	Meropenem 500mg Iv			C				Not Reported	
	Acetaminophen 650mg Po			C				Not Reported	
	Aspirin 81mg Po			C				Not Reported	

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Atorvastatin 40mg Po	C	Not Reported
Enoxaparin 40mg Sc	C	Not Reported
Gabapentin 300mg Po	C	Not Reported
Hydroxychlorothiazide 25mg Po	C	Not Reported
Levothyroxine 25 Mcg Po	C	Not Reported
Lisinopril 40mg Po	C	Not Reported
Sertraline 50mg	C	Not Reported
Azithromycin 500mg Iv	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17801911	DIRECT						Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use	Hydroxychloroquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	11179339	EXPEDITED (15-DAY)		OT	CA-ROCHE-1590696		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Swelling;	Rituximab			S	Intravenous drip			Not Reported
Candida Infection;	Enbrel			S	Subcutaneous			Not Reported
Candida Infection;	Orencia			S	Subcutaneous			Not Reported
Condition Aggravated;	Arava			S	Unknown			Not Reported
Contraindicated Product	Arava			S				Not Reported
Administered; Drug	Celebrex			S	Unknown			Not Reported
Ineffective; Drug	Celebrex			S				Not Reported
Interaction; Drug	Methotrexate Sodium			S	Unknown			Not Reported
Interaction; Drug	Prednisone			S	Unknown			Not Reported
Interaction; Hepatotoxicity;	Plaquenil [Hydroxychloroquine			S	Unknown	Therapy Duration: 3 Years		Not Reported
Joint Swelling; Joint	Sulfate]							
Swelling; Loss Of	Leflunomide			S	Oral	Therapy Duration: 9		Not Reported
Personal Independence In						Months		
Daily Activities; Nausea;								
Neoplasm Malignant;	Leflunomide			S	Oral			Not Reported
Neoplasm Malignant; Oral								
Candidiasis; Pain;	Sulfasalazine			S	Unknown	Therapy Duration: 3 Years		Not Reported
Peripheral Swelling;								
Rheumatoid Arthritis;								

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Rheumatoid Arthritis; Swelling; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Thyroid Neoplasm; Thyroid Neoplasm; Toxicity To Various Agents; Toxicity To Various Agents	Sulfasalazine Sulfasalazine Methotrexate Methotrexate Methotrexate Apo-Leflunomide Apo-Leflunomide Apo-Leflunomide Apo-Prednisone Hydroxychloroquine Hydroxychloroquine Sulfate Actemra Humira Xeljanz	S S S S S S S S S S S S S S C	Unknown Unknown Subcutaneous Subcutaneous Subcutaneous Oral Oral Oral Unknown Unknown Unknown Subcutaneous Unknown Oral	Therapy Duration: 13 Years	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	12117854	EXPEDITED (15-DAY)		OT	CA-ROCHE-1630803		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown	Stopped		Not Reported
Abdominal Discomfort; Back Pain; Blood Pressure Increased; Bone Disorder; Contusion; Crying; Drug Ineffective; Dysphagia; Femur Fracture; Gait Disturbance; Haemorrhage; Hypersensitivity; Immune System Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Hypersensitivity;	Rituxan Enbrel Enbrel Humira Methotrexate Plaquenil [Hydroxychloroquine Sulfate] Xeljanz Arava			S S S S S S S S	Intravenous (not otherwise specified) Subcutaneous Subcutaneous Subcutaneous Unknown Unknown Oral Oral	Stopped. Cyclical		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Intervertebral Disc Degeneration; Oedema Peripheral; Osteoarthritis; Osteoporosis; Pain; Pruritus; Rash; Swelling	Prednisone	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	12146308	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2016130747		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated;	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
Contraindicated Product Administered; Disability;	Pantoloc			S	Unknown	40 Milligram, Qd		Pfizer
Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury;	Enbrel			S	Subcutaneous	Unk		Pfizer
Haematocrit Decreased; Haemoglobin Decreased;	Etanercept			S		Unk		Pfizer
Joint Swelling;	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
Musculoskeletal Pain;	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
Pain In Extremity;	Methotrexate Sodium			S	Oral	20 Milligram, 1/Week		Pfizer
Peripheral Swelling; Rash;	Methotrexate Sodium			S	Oral	25 Milligram, 1/Week		Pfizer
Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	25 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	25 Milligram		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	Unk, Q2weeks		Pfizer
	Methotrexate Sodium			S	Oral	20 Milligram, Qd		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	1000 Milligram, Bid		Pfizer
	Sulfasalazine			S	Oral	500 Milligram, Bid		Pfizer
	Pantoprazole Sodium Anhydrous			S		40 Mg, 1x/Day		Not Reported
	Pantoprazole Sodium Sesquihydrate			S		40 Mg, 1x/Day		Not Reported
	Apo-Folic Acid			S		5 Mg, 2x/Week		Not Reported
	Apo-Folic Acid			S		5 Mg, 2x/Week		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Co Atenolol	S		25 Milligram, Qd	Not Reported
Co Atenolol	S		20 Milligram, Qd	Not Reported
Atenolol	S		25 Mg, 1x/Day	Not Reported
Naprosyn	S	Oral	100 Milligram, Qd	Not Reported
Naprosyn	S	Oral	500 Milligram, Bid	Not Reported
Naprosyn	S	Oral	500 Mg, 2x/Day	Not Reported
Naprosyn	S	Oral	1000 Mg, 1x/Day	Not Reported
Naproxen	S	Oral	100 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Qd	Not Reported
Naproxen	S	Oral	500 Milligram, Bid	Not Reported
Palafer Cf	S	Unknown	Unk, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Plaquenil	S	Unknown	400 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	40 Milligram, Qd	Not Reported
Plaquenil	S	Unknown	200 Milligram, Bid	Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole Teva	S	Unknown	Unk	Not Reported
Ferrous Fumarate W/Folic Acid	S	Unknown	Unk Unk, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	20 Milligram, Qd	Not Reported
Arava	S	Oral	Unk	Not Reported
Leflunomide	S	Oral	20 Mg, 1x/Day	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S		Unk	Not Reported
Adalimumab	S	Subcutaneous	Unk	Not Reported
Abatacept	S		Unk	Not Reported

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Ascorbic Acid	S		Unk, 1x/Day	Not Reported
Ferrous Fumarate	S	Unknown	Unk	Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid	Not Reported
Folic Acid	S	Unknown	5 Milligram, 2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S		200 Mg, 2x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, 1x/Day	Not Reported
Hydroxychloroquine Sulfate	S		40 Mg, Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd	Not Reported
Ferrous Fumarate/Folic Acid	S		Unk, 1x/Day	Not Reported
Remicade	S		Unk	Not Reported
Naproxen Sodium	S		500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S		1000 Mg, 1x/Day	Not Reported
Naproxen Sodium	S	Oral	500 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	100 Mg, 2x/Day	Not Reported
Naproxen Sodium	S	Oral	1000 Mg, 1x/Day	Not Reported
Hydroxychloroquine	S		400 Mg, Weekly	Not Reported
Hydroxychloroquine	S		40 Mg, Weekly	Not Reported
Palafer	S		Unk	Not Reported
Pantoprazole Sodium	S		40 Mg, 1x/Day	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C		Unk	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Celecoxib	C	Oral	Unk	Not Reported
Celecoxib	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	12197652	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1727368		83 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Contraindicated Product Administered; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Infection; Inflammation; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction; Nausea; Osteoarthritis; Osteopenia; Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural Thickening; Presbycusis; Renal Impairment; Rheumatoid Arthritis; Skin Lesion; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Oxycontin			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Oral			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]			C	Unknown			Not Reported
	Diphenoxylate			C	Unknown	2.5/0.025 Mg Daily		Not Reported
	Actonel			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Aclasta			C	Intravenous (not otherwise specified)			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Nasonex			C	Unknown	2 Sprays Intranasal		Not Reported
	Lomotil [Atropine Sulfate;Diphenoxylate			C	Unknown	3-4 Times/Day.		Not Reported

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Hydrochloride] Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride] Ergocalciferol	C	Unknown	1 Dosage Form	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown		Not Reported
Loperamide Hydrochloride	C	Unknown		Not Reported
Pantoprazole Magnesium	C	Unknown		Not Reported
Tylenol	C	Oral		Not Reported
Tylenol	C	Oral		Not Reported
Trazodone Hydrochloride	C	Oral		Not Reported
Perphenazine	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	12511500	EXPEDITED (15-DAY)		OT	CA-ROCHE-1784162			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Actemra			S	Unknown			Not Reported
Arthropathy; Bone	Crestor			S	Unknown			Not Reported
Erosion; Contraindicated	Enbrel			S	Subcutaneous			Not Reported
Product Administered;	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Diabetes Mellitus; Drug	Sulfate]							
Hypersensitivity; Drug	Arava			S	Unknown			Not Reported
Hypersensitivity; Drug	Orencia			S	Unknown			Not Reported
Ineffective; Drug	Remicade			S	Intravenous (not			Not Reported
Ineffective; Erythema;					otherwise specified)			
Hypersensitivity; Ill-								
Defined Disorder; Joint	Methotrexate Sodium			S	Unknown			Not Reported
Swelling; Peripheral	Apo-Hydroxyquine			S	Unknown			Not Reported
Swelling; Red Blood Cell	Apo-Azathioprine			S	Unknown			Not Reported
Sedimentation Rate	Azathioprine			S	Unknown			Not Reported
Abnormal; Rheumatoid	Cimzia			S	Subcutaneous			Not Reported
Factor Negative; Skin								
Laceration; Skin								
Laceration; Skin Ulcer;								
Swelling; Treatment								

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Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Oral	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	12919635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1851565		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis;	Actemra			S	Unknown			Not Reported
Arthropathy;	Kineret			S	Unknown			Not Reported
Contraindicated Product	Kineret			S	Unknown			Not Reported
Administered; Drug	Kineret			S	Subcutaneous			Not Reported
Ineffective; Joint Swelling;	Kineret			S	Unknown			Not Reported
Knee Arthroplasty; Pain;	Kineret			S	Unknown			Not Reported
Red Blood Cell	Enbrel			S	Subcutaneous			Not Reported
Sedimentation Rate	Humira			S	Unknown			Not Reported
Abnormal; Shoulder	Humira			S	Subcutaneous			Not Reported
Arthroplasty; Treatment	Apo-Hydroxyquine			S	Unknown			Not Reported
Failure	Infliximab			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Anakinra	S	Unknown	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Anakinra	S	Unknown	Not Reported
Anakinra	S	Oral	Not Reported
Desoximetasone	C	Unknown	Not Reported
Methotrexate	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Cortisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	12946333	EXPEDITED (15-DAY)		OT	CA-ROCHE-1853943		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Blood Cholesterol Increased; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Parenteral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Other	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Imuran [Azathioprine]	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Tofacitinib	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	13112057	EXPEDITED (15-DAY)		OT	CA-ROCHE-1876559		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug	Actemra			S	Subcutaneous	Therapy Duration: 8		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Hypersensitivity; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab	S	Intravenous (not otherwise specified)	Months	Not Reported
	Rituximab	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Methotrexate	S	Oral	Therapy Duration: 4 Years	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Arava	S	Unknown	Therapy Duration: 6 Months	Not Reported
	Apo-Hydroxyquine	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Meloxicam	C	Oral		Not Reported
	Xeljanz	C	Oral		Not Reported
	Prednisolone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	13178708	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886825			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Contraindicated Product Administered;	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Rheumatoid Arthritis; Syncope; Urticaria	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Oral	Qd	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown	Qwk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Qmo	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Therapy Duration: 396.0 Nos	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 16.0 Years	Not Reported
	Prednisone	C	Unknown		Not Reported
	Prevacid	C	Unknown		Not Reported
	Xeljanz	C	Oral	Therapy Duration: 7.0 Day(S)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	13210355	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178527		40 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Arava			S		20 Mg, Qd		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Mefenamic Acid			S	Unknown	400 Mg,Bid		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Sanofi
	Enbrel			S	Subcutaneous	50 Mg		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	1 Df		Not Reported
	Enbrel			S		Unk, Qw		Not Reported
	Enbrel			S		50 Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S		5 Mg, Bid		Not Reported
	Sulfasalazine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	13229065	EXPEDITED (15-DAY)		OT	CA-ROCHE-1892565		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Condition	Actemra	S	Unknown		Not Reported
Aggravated;	Arava	S	Unknown	4.0 Months	Not Reported
Contraindicated Product	Enbrel	S	Unknown		Not Reported
Administered; Drug	Methotrexate	S	Subcutaneous		Not Reported
Ineffective; Joint Swelling;	Orencia	S	Unknown		Not Reported
Musculoskeletal Disorder;	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Therapy Duration: 2.0 Year(S)	Not Reported
Nasopharyngitis;	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Neutropenia; Off Label Use; Platelet Count Decreased; Respiratory Tract Infection Viral;	Xeljanz	S	Oral	Therapy Duration 505.0 Day(S)	Not Reported
Rheumatoid Arthritis;	Xeljanz	S	Oral		Not Reported
Sinusitis; Skin Papilloma;	Hydroxychloroquine	S	Unknown		Not Reported
Sleep Disorder; Tendon Disorder;	Leflunomide	S	Unknown	Therapy Duration: 4.0 Month(S)	Not Reported
Thrombocytopenia	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Therapy Duration 2.0 Years	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Advil [Ibuprofen]	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Ketorolac	C	Unknown		Not Reported
	Naproxen	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	13233820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893888		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Condition	Actemra	S	Subcutaneous	Not Reported
Aggravated; Drug	Enbrel	S	Unknown	Not Reported
Ineffective; Frustration	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Tolerance Decreased; Ill-Defined Disorder; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Stiffness; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Rheumatoid Arthritis; Suicidal Ideation; Treatment Failure; Vein Disorder	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Fosamax	C	Unknown	Not Reported
	Ibuprofen	C	Unknown	Not Reported
	Lisinopril	C	Unknown	Not Reported
	Vitamin D3	C	Unknown	Not Reported
	Fosavance	C		Not Reported
	Synthroid	C	Unknown	Not Reported
	Alendronate Sodium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	13966976	EXPEDITED (15-DAY)		OT	CA-ROCHE-1992036			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug	Actemra			S	Subcutaneous			Not Reported
Ineffective; Drug-Induced Liver Injury;	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatotoxicity; Joint Swelling; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Pain In Extremity; Peripheral Swelling; Therapeutic Response Decreased	Methotrexate	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown	Therapy Duration: 245.0 Nos	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Solution	Not Reported
	Enbrel	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	14444966	EXPEDITED (15-DAY)		OT	CA-ROCHE-2056327		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthralgia; Back Pain; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Treatment Failure; Treatment Failure	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Leflunomide	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Ciclosporin	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Arava	C	Oral	Not Reported
Risedronate	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	14535636	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2018CA0135			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Kineret			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Apo-Mycophenolate			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S		Not Reported
Celebrex	S		Not Reported
Humira	S	Subcutaneous	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Cellcept	S		Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Methotrexate	C		Not Reported
Celebrex	C	Unknown	Not Reported
Humira	C		Not Reported
Prednisone	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	14539305	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0137			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthrodesis;	Kineret			S	Subcutaneous			Not Reported
Arthropathy;	Kineret			S	Unknown			Not Reported
Contraindicated Product	Enbrel			S	Subcutaneous			Not Reported
Administered; Drug	Orencia			S	Unknown			Not Reported
Ineffective; Joint Swelling;	Actemra			S	Unknown			Not Reported
Knee Arthroplasty; Off	Humira			S	Subcutaneous			Not Reported
Label Use; Pain; Red	Infliximab			S	Intravenous (not			Not Reported
Blood Cell Sedimentation								
Rate Abnormal; Shoulder								
Arthroplasty; Treatment								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Failure		otherwise specified)							
	Apo-Hydroxyquine	S							Not Reported
	Plaquenil	S	Oral						Not Reported
	Remicade	S	Intravenous (not otherwise specified)						Not Reported
	Remicade	S							Not Reported
	Simponi	S	Subcutaneous						Not Reported
	Simponi	S							Not Reported
	Sulfasalazine	S	Oral						Not Reported
	Hydroxychloroquine	S	Unknown						Not Reported
	Hydroxychloroquine	S							Not Reported
	Hydroxychloroquine Sulfate	S	Oral						Not Reported
	Tocilizumab	S	Subcutaneous						Not Reported
	Gold	S	Intramuscular						Not Reported
	Imuran	S							Not Reported
	Leflunomide	S	Oral						Not Reported
	Rituximab	S	Intravenous (not otherwise specified)						Not Reported
	Etanercept	S	Subcutaneous						Not Reported
	Methotrexate	S							Not Reported
	Methotrexate	C	Oral						Not Reported
	Methotrexate	C	Unknown						Not Reported
	Prednisone	C	Unknown						Not Reported
	Desoximetasone	C	Unknown						Not Reported
	Cortisone	C							Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	15009839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2137691		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Joint Swelling;	Actemra			S	Unknown	Therapy Duration: 2.0 Years		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neutropenia; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Enbrel	S	Subcutaneous	Therapy Duration: 3.0 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Cyclical	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Desoximetasone	C			Not Reported
	Orencia	C	Unknown	Therapy Duration: 5.0 Years	Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	15065924	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0717		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Operation; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Kineret			S	Unknown			Not Reported
	Kineret			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Enbrel			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	
Rituxan	S	Intravenous drip	Not Reported
Rituxan	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S		Not Reported
Actemra	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S		Not Reported
Bupropion	C	Oral	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	15356144	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2179236		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ilaris			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown	Solution For Injection		Not Reported
	Humira			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S				Not Reported
Remicade			S	Unknown			Not Reported	
Remicade			S				Not Reported	
Rituximab			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S		Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S		Not Reported
Methotrexate	C	Unknown	Not Reported
Rituximab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	15598301	EXPEDITED (15-DAY)		DS, OT	CA-SA-2018SA021997		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; C-Reactive Protein Increased;	Leflunomide			S	Oral	Unk Unk,Unk		Sanofi
Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased;	Methotrexate			S	Subcutaneous	15 Mg/M2,Unk		Not Reported
Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfasalazine			S	Unknown			Not Reported
	Abatacept			S	Unknown	Unk Unk, Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S		15 Mg Qwk		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Qwk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	420 Mg, Unk		Not Reported
	Infliximab			S	Unknown	200 Mg, Qwk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Cell Count Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	15781203	EXPEDITED (15-DAY)		OT	CA-SA-2018SA397121			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Sanofi
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil Sulfate			C				Not Reported
	Desoximetasone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	15832234	EXPEDITED (15-DAY)		DS	CA-ROCHE-1893094		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chondropathy; Disability; Drug Ineffective; Headache; Malaise; Sarcoidosis; Tooth Extraction; Tooth Fracture; Weight Increased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Unknown	Not Reported
Humira	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Xeljanz	C		Not Reported
Cephalexin [Cefalexin]	C	Unknown	Not Reported
Cephalexin Monohydrate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16008854	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016510		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac			S	Unknown			Actavis	
Adverse Event; Alopecia;	Diclofenac			S	Unknown			Actavis	
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Methotrexate			S	Oral			Barr	
Arthropathy; Condition Aggravated; Discomfort;	Methotrexate			S	Intra-arterial			Barr	
Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue;	Prednisone			S	Unknown			Actavis	
Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Inflammation;	Leflunomide			S	Unknown			Barr	
Intentional Product Use	Leflunomide			S	Oral			Barr	
	Paracetamol			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue; Joint Swelling;	Arava	S	Unknown		Not Reported
Knee Arthroplasty; Live	Cimzia Single-Use Prefilled	S	Subcutaneous		Not Reported
Birth; Maternal Exposure	Syringe				
During Pregnancy;	Cimzia Single-Use Prefilled	S			Not Reported
Musculoskeletal Stiffness;	Syringe				
Off Label Use; Pain;	Enbrel	S	Subcutaneous		Not Reported
Pemphigus; Pericarditis;	Enbrel	S	Subcutaneous		Not Reported
Rash; Rheumatoid	Folic Acid	S	Unknown		Not Reported
Arthritis; Rheumatoid	Fosamax	S	Oral		Not Reported
Factor Positive; Sinusitis;	Fosamax	S	Unknown		Not Reported
Swelling; Synovitis;	Humira	S	Subcutaneous		Not Reported
Systemic Lupus	Humira	S			Not Reported
Erythematous; Treatment	Hydroxychloroquine Sulfate	S	Oral		Not Reported
Failure; Wound	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily;	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Unknown		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine	S			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfate]]									
Pseudoephedrine Hcl	S	Unknown							Not Reported
Sulfasalazine	S	Unknown	2 Gram Daily;						Not Reported
Sulfasalazine	S	Unknown							Not Reported
Topicort Mild (Desoximetasone)	S	Oral							Not Reported
Topicort Mild (Desoximetasone)	S	Unknown							Not Reported
Apo-Prednisone	S	Unknown							Not Reported
Apo-Prednisone	S								Not Reported
Apo Folic	S	Unknown							Not Reported
Apo Hydroxyquine	S	Unknown	400 Milligram Daily;						Not Reported
Sarilumab	S	Unknown							Not Reported
Stelara	S	Unknown							Not Reported
Sulfathalidine	S	Subcutaneous							Not Reported
Xeljanz	S	Unknown	10 Milligram Daily;						Not Reported
Xeljanz	S								Not Reported
Desoximetasone	S	Oral							Not Reported
Leflunomide	C	Unknown							Not Reported
Atasol	C	Unknown							Not Reported
Salazopyrin	C	Unknown							Not Reported
Tofacitinib Citrate	C	Unknown							Not Reported
Acetaminophen	C	Unknown							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16226845	EXPEDITED (15-DAY)		HO, OT	CA-SA-2019SA110472			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Multiple Fractures; Osteoporosis;	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	Unk		Sanofi
	Naproxen			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra	S		Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Folic Acid	C			Not Reported
	Methotrexate	C		20 Mg	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16231995	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110775			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Hydroxychloroquine			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported
	Orencia			S				Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tocilizumab			S				Not Reported
	Xeljanz			S				Not Reported
	Prednisone			C	Unknown	10 Mg		Not Reported
	Cimzia			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16425615	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1061416		70 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Myopathy Toxic	Hydroxychloroquine			S	Unknown	200 Milligram Daily;		Teva
	Losartan			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16645870	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202595			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lung Disorder; Respiratory Disorder; Rheumatoid Arthritis	Hydroxychloroquine			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S		Solution Intravenous		Not Reported
	Leflunomide			S				Sanofi
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Desoximetasone			C		Not Specified		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16646742	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202696		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Inflammatory Marker Increased; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Musculoskeletal Stiffness;	Plaquenil			S	Oral			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Sanofi
	Hydroxychloroquine			S	Subcutaneous	Unk, Qow		Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress	Enbrel	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Enbrel	S	Subcutaneous	Unk, Duration: 129	Not Reported
	Cimzia	S	Subcutaneous	Unk Unk, Qw	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Prednisone	C	Oral	6 Mg, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported
	Mefenamic Acid	C			Not Reported
	Dequalinium Chloride	C			Not Reported
	Tylenol [Paracetamol]	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16650735	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202940		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non- Hodgkin'S Lymphoma	Hydroxychloroquine			S		Unk		Sanofi
	Arava			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Minocycline Hydrochloride			S		Unk		Not Reported
	Sulfasalazine			S		Unk		Not Reported
	Apo-Azathioprine			S		100 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

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Xeljanz			S		5 Mg, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16650736	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202974			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine			S	Oral	400 Mg, Qw		Sanofi	
	Hydroxychloroquine			S	Oral	200 Mg, Qow		Sanofi	
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi	
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Sanofi	
	Plaquenil			S	Oral	200 Mg, Bid		Sanofi	
	Arava			S	Oral	20 Mg, Qd		Sanofi	
	Methotrexate			S	Oral	20 Mg, Qw		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Xeljanz			C				Not Reported	
	Folic Acid			C	Oral	5 Mg		Not Reported	
	Prednisone			C	Oral			Not Reported	
	Tofacitinib Citrate			C				Not Reported	
	Leflunomide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16650744	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202752		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Neck Pain	Plaquenil			S				Sanofi	
	Methotrexate			S				Not Reported	
	Arava			S				Sanofi	
	Actemra			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enbrel	S			Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S			Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Mobicox	C	15 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16651231	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202759		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Hydroxychloroquine Sulfate			S	Unknown	5 Mg, Unk		Sanofi
	Leflunomide			S	Unknown	5 Mg		Sanofi
	Leflunomide			S	Oral	10 Unk		Sanofi
	Methotrexate			S	Unknown	5 Mg, Unk		Not Reported
	Cimzia			S	Subcutaneous	200 Mg, Cyclical, Single Use Pre-Filled Syringe		Not Reported
	Enbrel			S	Unknown	50 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Qcy, Cyclical		Not Reported
	Orencia			S	Unknown	750 Mg		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Prednisone			C	Unknown	50 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16651242	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202767		8 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; C- Reactive Protein	Plaquenil			S				Sanofi

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Increased; Contraindicated Product	Leflunomide	S	Oral		Sanofi
Administered; Deformity;	Methotrexate	S	Subcutaneous	15 Mg/M2, Qw	Not Reported
Disability; Drug Ineffective;	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
General Physical Health	Sulfasalazine	S			Not Reported
Deterioration; Infusion Site	Rituximab	S	Intravenous (not otherwise specified)	420 Mg	Not Reported
Reaction; Joint					
Destruction; Joint Effusion;	Rituximab	S		Unk	Not Reported
Juvenile Idiopathic	Tocilizumab	S			Not Reported
Arthritis; Mean Cell	Tocilizumab	S			Not Reported
Haemoglobin Decreased;	Orencia	S			Not Reported
Mean Cell Volume	Orencia	S			Not Reported
Decreased; Mean Platelet	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Qw	Not Reported
Volume Decreased;					
Monocyte Count	Infliximab	S	Intravenous (not otherwise specified)	200 Mg, Qm	Not Reported
Increased;					
Musculoskeletal	Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Deformity; Osteoarthritis;	Humira	S	Subcutaneous	40 Mg, Qw	Not Reported
Pain; Physical Disability;	Adalimumab	S	Subcutaneous	40 Mg, Qw	Not Reported
Platelet Count Increased;	Adalimumab	S		Unk	Not Reported
Product Use Issue; Red	Actemra	S			Not Reported
Blood Cell Sedimentation	Enbrel	S			Not Reported
Rate Abnormal; Red Blood	Enbrel	S	Subcutaneous	15 Mg, Qw	Not Reported
Cell Sedimentation Rate	Etanercept	S		15 Mg, Qw	Not Reported
Increased; Red Cell	Etanercept	S	Subcutaneous	15 Mg, Qw	Not Reported
Distribution Width	Abatacept	S			Not Reported
Decreased; Red Cell	Abatacept	S			Not Reported
Distribution Width					
Increased; Rheumatoid					
Arthritis; Treatment					
Failure; Vascular Access					
Complication; White Blood					
Cell Count Increased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16651276	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202864			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling;	Hydroxychloroquine			S	Oral	600 Mg, Qd [1 Every 1 Day(S)]		Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Peripheral Swelling; Rheumatoid Arthritis	Hydroxychloroquine	S	Oral	20 Mg, Qd	Sanofi
	Arava	S	Oral	20 Mg, Qd [1 Every 1 Day(S)]	Sanofi
	Methotrexate	S	Oral	10 Mg, Qw [1 Every 1 Week(S)]	Not Reported
	Actemra	S			Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	C	Unknown	1 Df, Qw [1 Every 1 Week(S)]	Not Reported
	Prednisone	C			Not Reported
	Simponi	C	Subcutaneous	Formulation: Solution	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd [2 Every 1 Day(S)]	Not Reported
	Xeljanz	C	Oral	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16655167	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202673			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Hydroxychloroquine			S	Unknown	2 Df, Bid,200 Mg		Sanofi
	Arava			S	Unknown	Unk Unk, Unk		Sanofi
	Methotrexate			S	Unknown	25 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Humira			S	Unknown	200 Mg, Biw, Solution Subcutaneous		Not Reported
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported
	Orencia			S	Unknown	Unk Unk, Unk		Not Reported
	Tocilizumab			S	Unknown	Unk Unk, Unk		Not Reported
	Sodium Aurothiomalate			S	Intramuscular	Unk Unk, Unk, Solution Intramuscular		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Qm		Not Reported

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Xeljanz	S	Unknown	Unk Unk, Unk	Not Reported
Desoximetasone	C	Unknown	Unk Unk, Unk	Not Reported
Darifenacin Hydrobromide	C	Unknown	Unk Unk, Unk	Not Reported
Darifenacin	C	Unknown	Unk Unk, Unk	Not Reported
Ativan	C	Unknown	Unk Unk, Unk	Not Reported
Codeine	C	Unknown	Unk Unk, Unk	Not Reported
Anakinra	C	Unknown	Unk Unk, Unk	Not Reported
Dexamethasone	C	Unknown	Unk Unk, Unk	Not Reported
Dilaudid	C	Unknown	Unk Unk, Unk	Not Reported
Diphenhydramine	C	Unknown	Unk Unk, Unk	Not Reported
Furosemide	C	Unknown	Unk Unk, Unk	Not Reported
Hydromorphone	C	Unknown	Unk Unk, Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	C	Unknown	Unk Unk, Unk, Suspension Intra-Articular	Not Reported
Loperamide	C	Unknown	Unk Unk, Unk	Not Reported
Morphine Sulphate	C	Unknown	Unk Unk, Unk	Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown	Unk Unk, Unk	Not Reported
Omnaris	C	Unknown	Unk Unk, Unk, Spray Metered Dose	Not Reported
Oxyneo	C	Unknown	Unk Unk, Unk, Tablet-Extended Release	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Unk Unk, Unk Tablet Enteric Coated	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk Unk, Unk	Not Reported
Restasis	C	Unknown	Unk Unk, Unk, Emulsion	Not Reported
Synthroid	C	Unknown	Unk Unk, Unk	Not Reported
Trimethoprim	C	Unknown	Unk Unk, Unk	Not Reported
Urispas	C	Unknown	Unk Unk, Unk	Not Reported
Vagifem	C	Unknown	Unk Unk, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16655179	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202618		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
	Plaquenil			S		400 Mg, Qd		Sanofi
	Folic Acid			S		Unk		Not Reported
	Folic Acid			S		5 Mg		Not Reported
	Folic Acid			S		1 Mg		Not Reported
	Prednisone			S		Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		10 Mg		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Methotrexate			S		20 Mg, Qd		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Pseudoephedrine Hydrochloride			S		Unk		Sanofi
	Arava			S	Oral	Unk		Sanofi
	Arava			S		Unk		Sanofi
	Cortisone Acetate			S		25 Mg		Not Reported
	Alendronate Sodium			S		Unk		Not Reported
	Sulfasalazine			S		500 Mg		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Cimzia			S		Subcutaneous	Unk	

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Orencia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfathalidine	S		Unk	Not Reported
Desoximetasone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Golimumab	S		Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Salazopyrin	C		Unk	Not Reported
Diclofenac	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16656983	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202972		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated;	Hydroxychloroquine			S	Oral	1 Df, Qd		Sanofi
Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause;	Plaquenil			S	Oral	1 Df, Qd		Sanofi
Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis;	Leflunomide			S	Oral	1 Df, Qd		Sanofi
	Leflunomide			S	Oral	1 Mg, Qd		Sanofi
	Arava			S		1 Df, Qd		Sanofi
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Mefenamic Acid			S		2 Df, Qd		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported

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Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure	Methotrexate	S		Unk	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Methotrexate	S	Oral	20 Mg, Qw	Not Reported
	Methotrexate	S		Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg	Not Reported
	Enbrel	S		Unk	Not Reported
	Enbrel	S		Unk Unk, Qw	Not Reported
	Enbrel	S		1 Df	Not Reported
	Enbrel	S		50 Mg	Not Reported
	Xeljanz	S	Oral	2 Df, Qd (5 Mg Stength)	Not Reported
	Xeljanz	S		Unk	Not Reported
	Xeljanz	S		2 Df, Qd	Not Reported
	Xeljanz	S		2 Df, Qd (5 Mg Stength)	Not Reported
	Sulfasalazine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16686491	EXPEDITED (15-DAY)		OT	CA-SA-2019SA209083			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Arava			S	Oral	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Oral	600 Mg, Qw		Sanofi
	Hydroxychloroquine			S	Oral	20 Mg, Qd		Sanofi
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Actemra			S	Unknown	Unk Unk, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Unk		Not Reported
	Folic Acid			C	Unknown	1 Df, Qw		Not Reported
	Prednisone			C	Unknown	Unk Unk, Unk		Not Reported
	Simponi			C	Unknown	Unk Unk, Unk		Not Reported

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Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz	C	Oral	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16710769	EXPEDITED (15-DAY)		OT	DE-ASTRAZENECA-2019SF17234			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole			S	Oral			Not Reported
	Omeprazole			S	Oral			Not Reported
	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Not Reported
	Ramipril			S	Oral			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Unknown			Not Reported
	Volibris			S	Oral			Not Reported
	Volibris			S	Oral			Not Reported
	Eliquis			S	Unknown			Not Reported
	Eliquis			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported
	Quensyl			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Sildenafil Citrate			S	Unknown			Not Reported
	Roactemra			S	Subcutaneous			Not Reported
	Roactemra			S	Subcutaneous			Not Reported
	Spasmolyt			S	Unknown			Not Reported
Spasmolyt			S	Unknown			Not Reported	

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Spasmolyt	S	Unknown	Not Reported
Spasmolyt	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16822887	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2019GSK067189		25 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Dermatitis; Headache; Herpes Zoster; Inappropriate Schedule Of Product Administration; Leukocytosis; Product Availability Issue; Product Dose Omission; Pyrexia; Rash; Skin Injury; Skin Lesion; Systemic Lupus Erythematosus; Urinary Tract Infection; Weight Decreased	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		Unk		Glaxosmithkline
	Belimumab			S		630 Mg, Unk		Glaxosmithkline
	Mycophenolate Sodium			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	16939747	EXPEDITED (15-DAY)		OT	CA-ROCHE-2436179		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Neoral	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Ciclosporin	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17037780	EXPEDITED (15-DAY)		LT	CA-ROCHE-2461506			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthralgia; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Juvenile Idiopathic Arthritis; Mobility Decreased; Nausea; Obesity; Off Label Use;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	5.0 Month(S)		Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Triamcinolone			S	Intra-articular			Not Reported
	Triamcinolone			S				Not Reported
	Enbrel			S	Subcutaneous	7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous	2.0 Month(S)		Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prescribed Underdose; Product Use In	Infliximab	S	Intravenous (not otherwise specified)	4.0 Month(S)	Not Reported
Unapproved Indication; Psoriasis; Quality Of Life	Kineret	S	Subcutaneous	1.0 Year(S)	Not Reported
Decreased; Red Blood Cell Sedimentation Rate	Kineret	S			Not Reported
Increased; Septic Shock; Synovitis; Therapy Non- Responder; Vomiting; Wheelchair User	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	2.0 Month(S)	Not Reported
	Orencia	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S			Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Anakinra	S	Subcutaneous		Not Reported
	Anakinra	S	Unknown		Not Reported
	Folic Acid	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17132363	EXPEDITED (15-DAY)		OT	CA-ROCHE-2489219			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non- Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Minocycline Hydrochloride	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Amoxicillin	C	Unknown	Not Reported
Amoxicillin Trihydrate; Clavulanate Potassium	C	Unknown	Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Bcg Vaccine	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17134891	EXPEDITED (15-DAY)	LT		CA-ROCHE-2485918		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Actemra			S	Unknown			Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Actemra			S				Not Reported
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disease; Joint Swelling;	Arava	S	Unknown	Not Reported
Myocardial Infarction; Off	Arava	S	Unknown	Not Reported
Label Use; Pain;	Enbrel	S	Subcutaneous	Not Reported
Photosensitivity Reaction;	Enbrel	S		Not Reported
Pulmonary Embolism;	Gold	S	Unknown	Not Reported
Pulmonary Thrombosis;	Humira	S	Unknown	Not Reported
Red Blood Cell	Humira	S	Subcutaneous	Not Reported
Sedimentation Rate	Ilaris	S	Subcutaneous	Not Reported
Increased; Renal Failure;	Ilaris	S		Not Reported
Sepsis; Stomatitis;	Leflunomide	S	Unknown	Not Reported
Terminal State;	Leflunomide	S	Unknown	Not Reported
Thrombosis; Urticaria	Marijuana	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxycodone	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Sodium Aurothiomalate	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S		Not Reported
Cannabis Sativa	S	Unknown	Not Reported
Kineret	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17154597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2456781		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution		Not Reported
	Prednisone			C				Not Reported
	Prevacid			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17233345	EXPEDITED (15-DAY)	OT		CA-ROCHE-2508677		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product	Actemra			S	Unknown			Not Reported	
Administered; Drug	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
Hypersensitivity; Drug	Enbrel			S	Subcutaneous			Not Reported	
Ineffective; Drug	Humira			S	Subcutaneous			Not Reported	
Intolerance; Headache;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Rheumatoid Arthritis;	Leflunomide			S	Unknown			Not Reported	
Therapeutic Product Effect	Methotrexate			S	Unknown	10 Mg, 15 Mg		Not Reported	
Incomplete; Tremor	Remicade			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Pantoprazole Magnesium			C	Unknown			Not Reported	
	Tenofovir Disoproxil Fumarate			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Zopiclone			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17250077	EXPEDITED (15-DAY)	OT		CA-ROCHE-2517539			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17265226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516327		24 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Contraindicated	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Apo-Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methylprednisolone	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17310198	EXPEDITED (15-DAY)		OT	CA-ROCHE-2528070		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Dermatitis Allergic; Investigation Abnormal; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sleep Disorder; Synovitis; Treatment Failure	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Septra	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17349762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532663			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Condition Aggravated; Contraindicated Product Administered; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Impaired Gastric Emptying; Influenza; Off Label Use; Renal Impairment; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17364086	EXPEDITED (15-DAY)		LT	CA-ROCHE-2537110			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apparent Death; Deep Vein Thrombosis;	Actemra	S	Unknown	Not Reported
Diverticulitis; Drug Ineffective; Joint Swelling;	Actemra	S		Not Reported
Off Label Use; Pain;	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Pulmonary Embolism;	Rituxan	S		Not Reported
Renal Failure	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Ilaris	S	Subcutaneous	Not Reported
	Ilaris	S		Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17391683	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536704			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Rash	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S				Not Reported
	Gabapentin			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17654444	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2020-017303		76 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Abnormal; Breast Cancer Metastatic; Burning Sensation; Constipation; Dementia Alzheimer'S Type; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Plaquenil			S	Unknown	3 Dosage Form		Not Reported
	Plaquenil			S	Unknown	2 Dosage Form, Two Times A Day (One In Morning And One In Evening)		Not Reported

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Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus; Toe Amputation	Plaquenil	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17668617	EXPEDITED (15-DAY)		LT, OT	FR-ADVANSZ PHARMA- 202003002364			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alkalosis; Alkalosis; Atrial Flutter; Deep Vein Thrombosis; Drug Level Increased; Enterococcal Infection; Haematuria; Haemoglobin Decreased; Hyperglycaemia; Hypoxia; Off Label Use; Pneumonia Bacterial; Quadriparesis; Staphylococcal Infection; Vascular Device Infection	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600 Mg, Qd Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		600mg In The Morning, 400mg In The Evening Film-Coated Tablet		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		400 Mg, Qd Film-Coated Tablet		Concordia
	Lovenox			S	Subcutaneous	0.6 MI, Bid (Q12h)		Not Reported
	Lovenox			S	Subcutaneous	0.7 MI, Qd		Not Reported
	Lovenox			S	Subcutaneous	1.4 MI, Qd		Not Reported
	Paracetamol			S		4 G, Qd		Not Reported
	Paracetamol			S				Not Reported
	Movicol			C		Unk		Not Reported
	Dexamethasone			C		Unk		Not Reported
	Lasilix			C		Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Pantoprazole			C				Not Reported
	Tienam			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17673548	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR- APL-2020-017887		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Death	Levofloxacin Arrow Film-Coated Tablets 500mg	S	Oral	2 Dosage Form, Once A Day	Aurobindo
	Sandoz Amoxi Clav	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Lovenox	S	Subcutaneous	1 Dosage Form, Once A Day	Not Reported
	Primperan	S	Oral	1 Dosage Form	Not Reported
	Ritonavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Azithromycin Sandoz [Azithromycin]	S	Oral	4 Dosage Form, Once A Day	Not Reported
	Doliprane	S	Oral	1 Dosage Form	Not Reported
	Plaquenil	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Darunavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17678836	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017962		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged	Levofloxacin Arrow Film-Coated Tablets 500mg			S	Oral	1000 Milligram, Once A Day		Aurobindo
	Levofloxacin Arrow Film-Coated Tablets 500mg			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17730463	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589860			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Contraindicated Product Administered; Drug Ineffective; Nasopharyngitis; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17732452	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590075		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported

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Intolerance; Glaucoma;	Enbrel	S	Unknown		Not Reported
Hepatic Enzyme	Enbrel	S	Unknown	190.0 Days	Not Reported
Increased;	Hydroxychloroquine	S	Unknown		Not Reported
Hypersensitivity;	Infliximab	S	Unknown		Not Reported
Hypertension; Limb	Leflunomide	S	Unknown		Not Reported
Discomfort; Off Label Use;	Methotrexate	S	Unknown		Not Reported
Pneumonia; Product Use	Methotrexate	S	Unknown		Not Reported
In Unapproved Indication;	Methotrexate	S	Unknown		Not Reported
Skin Reaction; Synovitis;	Orencia	S	Unknown		Not Reported
Thyroid Disorder;	Otezla	S	Unknown		Not Reported
Treatment Failure;	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Vomiting	Simponi	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulphate	S	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Dorzolamide	C	Unknown		Not Reported
	Hydrochloride/Timolol Maleate	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Estradiol	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Estrogel	C	Unknown		Not Reported
	Furosemide	C	Unknown		Not Reported
	Morphine	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Xalatan	C	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Zingiber Officinale	C	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetaminophen	C	Unknown	Not Reported
Baclofen	C	Unknown	Not Reported
Tofacitinib Citrate	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17749115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2592718			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Hepatotoxicity; Joint Swelling; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17751944	EXPEDITED (15-DAY)		OT	CA-ROCHE-1710933		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil [Hydroxychloroquine Sulfate]	S	otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17752813	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1045214		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Dolquine			S	Other	400 Mg Dia		Mylan
	Dolquine			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17752858	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1045229		65 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Drug Interaction; Off Label Use; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Qd		Mylan
	Ceftriaxona /00672201/			C	Intravenous (not otherwise specified)	1 Gram, Qd		Mylan
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17754839	EXPEDITED (15-DAY)		OT	CA-ROCHE-1674787		60 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)	Solution Intravenous		Not Reported
	Kineret			S	Subcutaneous	100mg Per Syringe Singleuse, Preservativefree Prefilled Syringes		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 107 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Anakinra	S	Subcutaneous	Not Reported
Anakinra	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17757977	EXPEDITED (15-DAY)		DS, HO, OT	CA-JNJFOC-20200500983			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abscess; Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatic Fibrosis; Interstitial Lung Disease; Joint Swelling; Rheumatoid Arthritis; Sepsis; Spinal Cord Infection	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S				Not Reported
	Azathioprine			S				Not Reported
	Diclofenac			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Mobicox			S				Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Naproxen			S				Not Reported
	Sulfasalazine			S				Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Intramuscular			Not Reported
	Plaquenil /00072602/ Prednisone			C				Not Reported
				C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17757978	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500977		72 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inflammation; Joint Stiffness; Joint Swelling; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Musculoskeletal Pain; Musculoskeletal Stiffness; Pain	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Prednisone			C				Not Reported	
	Sulfasalazine			C				Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17757979	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200500971		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Blood Glucose Abnormal; Clostridium Difficile Infection; Contusion; Dehydration; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Dysphonia; Gait Disturbance; Joint Swelling; Loss Of Consciousness; Nasopharyngitis; Oropharyngeal Pain; Pain; Productive Cough; Secretion Discharge;	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

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Sputum Discoloured; Thrombosis	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Warfarin Sodium	S	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17757980	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200500974		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Crohn'S Disease; Drug Ineffective; Elbow Operation; Inappropriate Schedule Of Product Administration; Neck Pain; Off Label Use; Pain In Extremity; Product Dose Omission; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Naproxen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17758008	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200500964		52 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17758010	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500966			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Bupropion	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17758054	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437417		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease; Diarrhoea; Gastrointestinal Disorder; Iron Deficiency Anaemia; Joint Effusion; Mouth Ulceration; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Tuberculin Test Positive	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17758059	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437409		54 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Drug Resistance; Hip Arthroplasty; Pulmonary Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Rituximab Gp2013			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17764530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596720		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

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Arava	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17765745	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500989			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Drug Ineffective; Localised Infection; Lung Disorder; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Gold			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17765811	EXPEDITED (15-DAY)		HO	CA-ROCHE-2591759			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Back Injury;	Rituximab			S	Intravenous (not			Not Reported

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Contraindicated Product Administered; Drug Ineffective; Fall; Headache; Liver Function Test Increased; Nausea; Product Label Confusion; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Tocilizumab	S	Unknown	otherwise specified)	Not Reported
	Arava	S	Unknown		Not Reported
	Azathioprine Sodium	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported
	Etanercept	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17771016	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1045647		66 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Plaquenil /00072603/			S	Oral	600 Milligram, Qd		Mylan
	Zithromax			S	Oral	500 Milligram, Qd		Mylan
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Mylan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17782453	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020161893		61 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Covid-19; Diarrhoea; Febrile Neutropenia; Fusobacterium Infection; Mucosal Inflammation; Nausea	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	125 Mg		Pfizer	
	Carboplatin			S	Other	750 Unk, Daily(1/3 Weeks)		Pfizer	
	Carboplatin			S	Other	750 Unk, Daily(1/3 Weeks)		Pfizer	
	Carboplatin			S	Other	600 Unk, Daily(1/3 Weeks)		Pfizer	
	Etoposide			S	Unknown	213 Unk(Day 1,2,3 3 Weeks)		Not Reported	
	Etoposide			S	Unknown	213 Unk(Day 1,2,3 3 Weeks)		Not Reported	
	Etoposide			S		165 Unk(Day 1,2,3 3 Weeks)		Not Reported	
	Nivolumab			S	Unknown	360, 1/3 Weeks		Not Reported	
	Nivolumab			S		360, 1/3 Weeks		Not Reported	
	Nivolumab			S	Unknown	360, 1/3 Weeks		Not Reported	
	Hydroxychloroquine			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Clavulanate Potassium			C	Unknown	Unk		Not Reported	
	Clavulanate Potassium			C	Unknown	Unk		Not Reported	
	Clavulanate Potassium			C	Unknown	Unk		Not Reported	
	Piperacillin Sodium			C	Unknown	Unk		Not Reported	
	Ciprofloxacin			C	Unknown	Unk		Not Reported	
	Ciprofloxacin			C	Unknown	Unk		Not Reported	
	Amoxicillin			C	Other	Unk		Not Reported	
	Amoxicillin			C	Other	Unk		Not Reported	
	Amoxicillin			C	Other	Unk		Not Reported	
	Tazocel			C	Intravenous (not	Unk		Not Reported	

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			otherwise specified)		
Ceftriaxone	C	Unknown	Unk		Not Reported
Metronidazole	C	Unknown	Unk		Not Reported
Cefepime	C	Intravenous (not otherwise specified)	Unk		Not Reported
Tazobactam	C		Unk		Not Reported
Oxygen	C	Unknown	Unk		Not Reported
Quetiapine	C		50 Mg		Not Reported
Buscapina	C		30 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17800342	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005269			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Mycophenolate Mofetil			C		Unk		Not Reported
	Prednisone			C				Not Reported
	Ceftriaxone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801059	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597847			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801162	EXPEDITED (15-DAY)		OT	CA-SA-2020SA122504			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown			Sanofi
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Bisoprolol Salt Not Specified			S	Unknown			Not Reported
	Pethidine Hydrochloride			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Erythromycin			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Sanofi
	Norfloxacin			S	Unknown			Not Reported
	Plaquenil			S	Oral	400 Mg		Sanofi
	Levofloxacin			S	Unknown			Not Reported
	Arthrotec			S	Unknown			Not Reported
	Arthrotec			S	Intracardiac			Not Reported
	Ceclor			S	Unknown			Not Reported

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	Celebrex		S	Oral	200 Mg, Qd		Not Reported
	Humira		S	Subcutaneous	400 Mg		Not Reported
	Lyrica		S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801165	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247402		57 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia ()		Sun
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported
	Lopinavir/Ritonavir			S	Oral	2u Cada 12h ()		Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801207	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- GSH201806-001951			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthrodesis; Fatigue; Gait Disturbance	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Meloxicam			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801367	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA- 202005005477			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602160			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Bupropion			C	Unknown			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
	Wellbutrin			C	Unknown	Tablet (Extendedrelease)		Not Reported	
	Wellbutrin			C	Oral			Not Reported	
	Xeljanz			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801454	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005382			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
	Sirolimus			C		Unk		Not Reported	
	Prednisone			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801559	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598903		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Alendronate Sodium			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Unknown			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Golimumab			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801562	EXPEDITED (15-DAY)		HO	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS- 050881			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Zydus Pharm
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported
	Loxen [Loxoprofen Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline [Norepinephrine]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox [Levofloxacin]			S	Subcutaneous	Unk		Not Reported
	Inexium [Esomeprazole Sodium]			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nimbex	C	Not Reported
Hypnovel	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801662	EXPEDITED (15-DAY)		DS, OT	CA-SA-2019SA202968		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthralgia;	Plaquenil			S	Unknown			Sanofi
C-Reactive Protein	Hydroxychloroquine			S	Unknown	400mg, Qd: 1 Every 1 Day (S)		Sanofi
Increased; Condition								
Aggravated; Disability;	Leflunomide			S	Unknown	20mg, Qd: 1 Every 1 Days (S)		Sanofi
Eye Disorder; Joint								
Swelling; Mobility	Methotrexate			S	Oral	20mg, Qw: 1 Every 1 Week(S)		Not Reported
Decreased;								
Musculoskeletal Pain;	Arava			S	Unknown			Sanofi
Ocular Toxicity; Off Label	Orencia			S	Unknown	125mg, Qw: 1 Every 1 Week(S)		Not Reported
Use; Pain In Extremity;								
Peripheral Swelling;	Enbrel			S	Unknown	50 Mg, Qw; 1 Every 1 Week(S)		Not Reported
Rheumatoid Arthritis;								
Swelling; Therapeutic	Humira			S	Subcutaneous	40mg, Qow : 1 Every 2 Week(S)		Not Reported
Product Effect Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17801713	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598629			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Off	Actemra			S	Unknown			Not Reported
Label Use; Pain;	Arava			S	Oral			Not Reported
Rheumatoid Arthritis;	Cimzia			S	Subcutaneous			Not Reported
Therapeutic Product Effect	Enbrel			S	Subcutaneous			Not Reported
Incomplete; Treatment	Humira			S	Subcutaneous			Not Reported
Failure	Hydroxychloroquine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Leflunomide	C	Oral	Not Reported
	Prednisone	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802035	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3408590-00		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gastrointestinal Pain	Kaletra 200/50			S	Oral			Not Reported	
	Hidroxicloroquina			S	Oral			Not Reported	
	Omeprazol			C	Oral			Not Reported	
	Paracetamol			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802249	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235824			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Topical			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazol	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802251	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236229			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Pre-Filled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan

S

Intravenous (not
otherwise specified)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802291	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020020250		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia;	Cimzia			S	Subcutaneous			Not Reported
Arthropathy; Blood	Actemra			S	Intravenous (not	Unk, Monthly (Qm)		Not Reported
Glucose Increased; Blood					otherwise specified)			
Pressure Diastolic	Actemra			S	Intravenous (not	800 Milligram, Monthly		Not Reported
Abnormal; Blood Pressure					otherwise specified)	(Qm)		
Diastolic Decreased;	Hydroxychloroquine Sulfate			S				Not Reported
Blood Pressure Diastolic	Methotrexate			S		20 Milligram, Weekly (Qw)		Not Reported
Increased; Blood Pressure								
Fluctuation; Blood	Rosuvastatin Calcium			S				Not Reported
Pressure Increased; Blood	Sulfasalazine			S				Not Reported
Pressure Systolic	Folic Acid			C				Not Reported
Increased; Bronchitis;	Humalog			C				Not Reported
Cardiac Disorder;	Sertraline Hydrochloride			C				Not Reported
Contusion; Croup	Synthroid			C				Not Reported
Infectious; Drug								
Ineffective; Fatigue;								
Fibromyalgia; Foot								
Deformity; Gastroenteritis								
Viral; Headache; Heart								
Rate Increased;								
Hypersensitivity;								
Hypertension;								
Hypotension;								
Immunosuppression;								
Influenza; Infusion Related								
Reaction; Insomnia;								
Musculoskeletal Stiffness;								
Nasopharyngitis; Nausea;								
Oropharyngeal Pain; Pain;								
Pain In Extremity;								
Pertussis; Productive								
Cough; Rash; Stress;								
Therapeutic Response								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Treatment
Failure; Weight
Decreased; Weight
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802319	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598683			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosis; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe.		Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802457	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236226			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Prednisone			S	Unknown			Actavis
	Methotrexate Sodium			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazol	S	Unknown	Not Reported
Plaquenil[Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802571	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600294			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onychoclasia; Tooth Loss	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cortisone Acetate			C	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802668	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600829			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802709	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235783		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Haemorrhage; Vessel Puncture Site Haemorrhage	Hidroxiclороquina (2143a)			S	Oral	400 Mg		Teva
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Acetilsalicilato De Lisina			S	Intravenous (not otherwise specified)	200 Mg		Not Reported
	Adiro 100 Mg Comprimidos Gastrorresistentes Efg , 500 Comprimidos			S	Oral	100 Milligram Daily; Cp		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802725	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601899		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab			S	Intravenous drip			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802741	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1236294		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral			Not Reported	
	Plaquenil 200 Mg, Comprime Pellicule			S	Oropharyngeal	200 Mg		Not Reported	
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802778	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236801		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration;	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Subcutaneous			Barr	
	Prednisone			S	Unknown			Actavis	
	Prednisolone			S	Unknown			Actavis	
	Risedronate Sodium			S	Unknown			Teva	

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Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra	S	Unknown		Not Reported
	Apo-Leflunomide	S	Oral	20 Milligram Daily;	Not Reported
	Arava	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Cyclobenzaprine	C	Unknown		Not Reported
	Desoximetasone	C	Unknown	5 Milligram Daily;	Not Reported
	Desoximetasone	C	Unknown		Not Reported
	Leflunomide	C	Unknown		Not Reported
	Prednisone Acetate	C	Unknown	5 Milligram Daily;	Not Reported
	Tylenol/00020001/	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802781	EXPEDITED (15-DAY)		HO	ES-ACCORD-182405		49 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600492		42 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Interstitial Lung Disease; Musculoskeletal Stiffness	Rituximab			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	3.0 Years		Not Reported	
	Sulfasalazine			S	Unknown	3.0 Years		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802794	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-182375		56 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hypoacusis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Azithromycin			S	Oral	500 Mg Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802827	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597599		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Osteoporotic Fracture; Spinal Compression Fracture	Actemra			S	Subcutaneous			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Tylenol			C	Unknown	Tablet (Extended Release)		Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802925	EXPEDITED (15-DAY)		OT	CA-ROCHE-1956506		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Drug Intolerance; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Nodule; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802931	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600444		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Treatment Failure; Uveitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

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Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Kevzara	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802958	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236215			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

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Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17802965	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236061			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematousus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo Prednison			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

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	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Hydrocortisone Acetate]	S	Topical	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803035	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA-202005005562			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803036	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA-202005005560			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803037	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA-202005005561			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803109	EXPEDITED (15-DAY)		HO, OT	ES-ACCORD-182473		48 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Colchicine			S	Oral	0.5 Mg Every 12 H		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803135	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236219		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Methotrexate			S	Unknown			Barr	
	Prednisone			S	Unknown			Actavis	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Phthalylsulfathiazole			S	Unknown			Not Reported	

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral 2 Gram Daily;	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803232	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503708		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypersensitivity	Otezla			S	Oral			Celgene	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Remicade			S	Intravenous drip			Not Reported	
	Stelara			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown	2 Dosage Forms		Not Reported	
	Methotrexate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803307	EXPEDITED (15-DAY)		HO, OT	US-ADVANTZ PHARMA-202005005559			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803317	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235961		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Atrioventricular Block First Degree	Hidroxyclorequina (2143a)	S	Oral	400 Milligram Daily;	Teva
	Hidrocortisona (54a)	S	Intravenous (not otherwise specified)	200 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803361	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237155		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus; Treatment Failure	Prednisone			S	Unknown			Actavis
	Tocilizumab			S	Unknown			Not Reported
	Sulfathalidine			S	Unknown			Not Reported
	Sulfasalazine			S	Oral	2000 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Plaquenil[Hydroxychloroquine Sulfate]			S	Unknown	400 Milligram Daily;		Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral	25 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported

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Desoximetasone	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cimzia Single-Use Prefilled Syringe	S	Subcutaneous	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803365	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598528		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis; Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Synovitis;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Rituxan			S				Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S				Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Terminal State; Thrombosis	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803486	EXPEDITED (15-DAY)		HO	ES-MYLANLABS- 2020M1045225		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Azithromycin			S				Not Reported	
	Dolquine			S	Oral	400 Mg Dia		Mylan	
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gr Dia		Mylan	
	Ceftriaxona /00672201/			S				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803596	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA- 202005005298			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Humira			S	Subcutaneous	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803597	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005393			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Cardiac Arrest; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
	Mycophenolate Mofetil			C		Unk		Not Reported	
	Prednisone			C		High Dose		Not Reported	
	Levofloxacin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803605	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-16827		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Rheumatoid Arthritis; Synovitis	Brenzys			S	Unknown	Unknown		Not Reported	
	Methotrexate Sodium			S	Oral	15 To 20 Mg (More Than Three Months)		Not Reported	
	Hydroxychloroquine			S	Unknown	200 To 400 Mg (More Than Three Months)		Not Reported	
	Orencia			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803681	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2595853		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction;	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	

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Joint Swelling; Loss Of	Enbrel	S	Subcutaneous	Not Reported
Personal Independence In	Enbrel	S	Unknown	Not Reported
Daily Activities;	Humira	S	Subcutaneous	Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine	S	Oral	Not Reported
Nail Disorder;	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Onychomadesis;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Onychomycosis	Infliximab	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803729	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597677			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Drug Ineffective; Off Label Use	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597892			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803809	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1048495		66 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Purpura; Thrombocytopenia	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Norepinephrine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium /01479302/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Lovenox			S	Subcutaneous	Unk		Mylan
	Plaquenil /00072603/			S	Oral	Unk		Mylan

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Loxen /00639802/	S	Intravenous (not otherwise specified)	Unk	Mylan
Sufentanil	C		Unk	Mylan
Nimbex /01302502/	C		Unk	Mylan
Hypnovel /00634101/	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803845	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598105		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803855	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235944			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand	Methotrexate			S	Unknown			Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported

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Deformity; Maternal	Cetirizine Hydrochloride	S	Unknown	Not Reported
Exposure During	Cimzia Single-Use Prefilled	S	Subcutaneous	Not Reported
Pregnancy; Pain;	Syringe			
Pemphigus; Product Use	Desoximetasone	S	Oral	Not Reported
Issue; Rash; Rheumatoid	Desoximetasone	S	Oral	Not Reported
Arthritis; Swelling;	Enbrel	S	Subcutaneous	Not Reported
Systemic Lupus	Folic Acid	S	Unknown	Not Reported
Erythematous; Wound	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram Daily; Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily; Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803880	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598433		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Actemra			S	Unknown			Not Reported	
Laboratory Test Abnormal	Leflunomide			S	Unknown			Not Reported	

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Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17803997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235976			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Drug Intolerance; Foot Deformity; Inguinal Hernia; Interstitial Lung Disease; Joint Dislocation; Periarticular Disorder; Post-Traumatic Neck Syndrome; Rheumatoid Arthritis	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Calcium Carbonate			S	Oral	3 Dosage Forms Daily;		Not Reported
	Methotrexate			S	Unknown			Barr
	Celebrex			S	Unknown	400 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Relafen			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown	3000 Milligram Daily;		Not Reported
	Magnesium Aspartate			C	Oral	3 Dosage Forms Daily;		Not Reported
	Omega 3 [Fish Oil]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804016	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236175			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease; Lupus-Like Syndrome; Swelling Face	Methotrexate			S	Unknown			Barr
	Mycophenolate Sodium			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804088	EXPEDITED (15-DAY)	HO		ES- GLAXOSMITHKLINE- ES2020079133		83 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hyponatraemia	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Glaxosmithkline
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2-2-2		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804295	EXPEDITED (15-DAY)	HO		CA-ROCHE-2598537		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Loss Of Personal Independence In Daily Activities; Pollakiuria; Product Dose Omission	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leucovorin [Folinic Acid]			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804335	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1048553		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Qd, 500 Mg Dia		Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	2 Gram, Qd, 2 Gr Dia		Mylan	
	Ceftriaxona /00672201/ Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd, 400 Mg Dia		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804502	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200503932		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate	Otezla			S	Oral			Celgene	
Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Entesopathy; Erythema;	Otezla			S	Oral	120 Milligram		Celgene	
	Otezla			S				Celgene	
	Actemra			S	Unknown	680 Milligram		Not Reported	
	Actemra			S	Unknown	360 Milligram		Not Reported	
	Actemra			S	Unknown	2.68 Milligram		Not Reported	
	Adalimumab			S	Subcutaneous	40 Milligram		Not Reported	
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported	
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported	
	Alendronic Acid			S	Unknown	70 Milligram		Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Apo-Ibuprofen			S	Oral			Not Reported	
	Apo-Leflunomide			S	Oral	500 Milligram		Not Reported	
	Apo-Leflunomide			S	Oral	380 Milligram		Not Reported	

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Granuloma Skin;	Apo-Leflunomide	S	Oral	20 Milligram	Not Reported
Headache;	Arava	S	Unknown		Not Reported
Hypercalcaemia;	Cimzia	S	Subcutaneous		Not Reported
Hypersensitivity;	Codeine	S	Unknown		Not Reported
Inflammation; Infusion	Cyclosporin	S	Unknown		Not Reported
Related Reaction; Infusion	Enbrel	S	Unknown	50 Milligram	Not Reported
Related Reaction; Loss Of	Enbrel	S	Subcutaneous		Not Reported
Personal Independence In	Enbrel	S	Unknown	25 Milligram	Not Reported
Daily Activities;	Enbrel	S	Unknown	25 Milligram	Not Reported
Musculoskeletal Disorder;	Humira	S	Subcutaneous	40 Milligram	Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine	S	Oral	20 Milligram	Not Reported
Nausea; Off Label Use;	Hydroxychloroquine	S	Oral	200 Milligram	Not Reported
Pain; Panniculitis;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Peripheral Swelling;	Ibuprofen	S	Oral	600 Milligram	Not Reported
Product Use Issue;	Ibuprofen	S	Oral	600 Milligram	Not Reported
Psoriatic Arthropathy;	Infliximab	S	Oral		Not Reported
Rash; Rash Pruritic; Red	Leflunomide	S	Oral	20 Milligram	Not Reported
Blood Cell Sedimentation	Leflunomide	S	Unknown	20 Milligram	Not Reported
Rate Increased;	Methotrexate	S	Oral	12 Milligram	Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Oral	10 Milligram	Not Reported
Rheumatoid Nodule; Skin	Methotrexate	S	Oral	25 Milligram	Not Reported
Necrosis; Skin Ulcer;	Methotrexate	S	Oral	10 Milligram	Not Reported
Synovitis; Tendonitis;	Methotrexate	S	Oral	10 Milligram	Not Reported
Tenosynovitis;	Methotrexate	S	Oral	10 Milligram	Not Reported
Therapeutic Product Effect	Methotrexate	S	Subcutaneous	70 Milligram	Not Reported
Decreased; Therapeutic	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
Product Effect Incomplete;	Methotrexate	S	Unknown	15 Milligram	Not Reported
Tongue Disorder; Ulcer	Methotrexate	S	Unknown	12 Milligram	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram	Not Reported

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Methotrexate	S	Unknown	10 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
Mogadon	S	Oral	5 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Myochrysine	S	Intramuscular	50 Milligram	Not Reported
Myochrysine	S	Intramuscular	25 Milligram	Not Reported
Orencia	S	Intravenous drip	760 Milligram	Not Reported
Orencia	S	Unknown	780 Milligram	Not Reported
Orencia	S	Subcutaneous		Not Reported
Remicade	S	Intravenous drip		Not Reported
Rituxan	S	Unknown	2000 Milligram	Not Reported
Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Subcutaneous		Not Reported
Sulfasalazine	S	Endocervical	500 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Tocilizumab	S	Unknown	680 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Diphenhydramine Hcl	C	Unknown		Not Reported
Colchicine	C	Oral		Not Reported
Dexilant	C	Oral		Not Reported
Febuxostat	C	Unknown		Not Reported

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	Folic Acid	C	Unknown		Not Reported
	Gravol	C	Unknown		Not Reported
	Nitrazepam	C	Unknown	5 Milligram	Not Reported
	Oxycodone	C	Unknown		Not Reported
	Prednisolone	C	Unknown	20 Milligram	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported
	Prednisolone	C	Unknown	20 Milligram	Not Reported
	Prednisolone	C	Unknown	10 Milligram	Not Reported
	Uloric	C	Unknown	160 Milligram	Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804544	EXPEDITED (15-DAY)		HO	ES-BAUSCH-BL-2020-014075		56 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrioventricular Block First Degree	Hydrocortisona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxiclороquina			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17804908	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020196604		64 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Tercian [Cyanemazine Tartrate]			S	Oral	25 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Daily		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 2x/Day (Every 12h)		Not Reported
	Paroxetine			C	Oral	30 Mg, Daily		Not Reported
	Depakine [Valproic Acid]			C	Oral	1000 Mg, Daily		Not Reported

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Aerius [Desloratadine]	C	Oral	5 Mg, Daily	Not Reported
Xanax	C	Oral	0.75 Mg, Daily	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805077	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198909		75 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycine			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805526	EXPEDITED (15-DAY)		HO	US-AMNEAL PHARMACEUTICALS-2020-AMRX-01419		39 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Covid-19	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Daily		Amneal

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805668	EXPEDITED (15-DAY)		HO	ES-ACCORD-182362		45 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Doxycycline			S	Oral	100 Mg Every 12 Hours		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	17805673	EXPEDITED (15-DAY)		HO	ES-ACCORD-182373		27 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

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Hepatitis	Hydroxychloroquine	S	Oral		Not Reported
	Ivermectin	S	Oral	12 Mg Du	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Hydroxychloroquine	S	Oral	800 Mg Day (Loading) Followed By 400 Mg Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17811689	DIRECT	N	HO			28 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Plaquenil Tab 200mg			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	13113133	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 0862		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis;	Methotrexate (Trade Name			S	Unknown			Not Reported
Arthropathy;	Unknown)							
Contraindicated Product	Methotrexate (Trade Name			S	Unknown			Not Reported
Administered; Drug	Unknown)							
Ineffective; Hepatic	Enbrel			S	Subcutaneous			Not Reported
Enzyme Increased; Joint	Enbrel			S	Unknown			Not Reported
Swelling; Loss Of	Actemra			S	Unknown			Not Reported
Personal Independence In	Actemra			S	Subcutaneous			Not Reported
Daily Activities;	Humira			S	Subcutaneous			Not Reported
Pneumonia; Prescribed	Humira			S	Subcutaneous			Not Reported
Underdose; Pulmonary	Humira			S	Subcutaneous			Not Reported
Fibrosis; Rheumatoid	Orencia			S	Unknown			Not Reported
Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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			otherwise specified)	
Remicade	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Rituxan	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Oral		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	13119212	EXPEDITED (15-DAY)		HO, OT	US-SA-2017SA004994		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Alprazolam			S	Oral	.5 Mg,Tid		Not Reported
Abdominal Pain; Adverse	Arava			S	Unknown	Unk Unk,Unk		Sanofi
Drug Reaction;	Lasix			S	Unknown	Unk Unk,Unk		Sanofi
Anaphylactic Reaction;	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
Appetite Disorder;	Isosorbide Dinitrate			S	Unknown	Unk Unk,Unk		Not Reported
Arthralgia; Arthritis	Ampicillin Sodium			S	Unknown	Unk Unk,Unk		Not Reported
Infective; Asthenia;	Flagyl			S	Unknown	Unk		Sanofi
Asthenia; Back Pain;	Mesalazine			S	Unknown	Unk		Sanofi
Blister; Chills;								
Constipation; Contusion;								
Diarrhoea; Dizziness;								

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Drug Hypersensitivity;	Citalopram Hydrobromide	S	Unknown	Unk	Not Reported
Drug Intolerance; Dry	Pregabalin	S	Oral	100 Mg,Hs	Not Reported
Skin; Dysphagia;	Cetirizine Hydrochloride	S	Unknown	10 Mg,Qd	Not Reported
Dysphoria; Dyspnoea; Ear	Ziprasidone Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
Pain; Erythema; Fatigue;	Ciprofloxacin Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
Gait Disturbance;	Colchicine	S	Unknown	Unk Unk,Unk	Not Reported
Haemorrhagic Diathesis;	Prochlorperazine	S	Unknown	Unk Unk,Unk	Not Reported
Hallucination; Headache;	Acetazolamide	S	Unknown	Unk Unk,Unk	Not Reported
Hypoaesthesia; Interstitial	Hydromorphone Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
Lung Disease; Intestinal	Doxycycline	S	Unknown	Unk Unk,Unk	Not Reported
Obstruction; Joint	Hydrochlorothiazide/Triamterene	S	Unknown	Unk Unk,Unk	Not Reported
Swelling; Loss Of	Erythromycin	S	Unknown	Unk Unk,Unk	Sanofi
Consciousness;	Hepatitis B Vaccine	S	Unknown		Not Reported
Musculoskeletal Stiffness;	Iron (Salt Not Specified)	S	Unknown	Unk Unk,Unk	Not Reported
Myalgia; Nausea; Neck	Cefalexin	S	Unknown	Unk Unk,Unk	Not Reported
Pain; Oedema; Oral Pain;	Methotrexate	S	Unknown	Unk Unk,Unk	Not Reported
Osteoarthritis; Pain;	Potassium Canrenoate	S	Unknown	Unk Unk,Unk	Not Reported
Photophobia; Pruritus;	Pseudoephedrine Hydrochloride	S	Unknown	Unk Unk,Unk	Sanofi
Rash; Rheumatoid	Sulfamethoxazole/Trimethoprim	S		Unk	Not Reported
Arthritis; Rhinorrhoea;	Sulfasalazine	S	Unknown	Unk Unk,Unk	Not Reported
Sjogren'S Syndrome; Skin	Oxcarbazepine	S	Unknown	Unk Unk,Unk	Not Reported
Disorder; Skin Warm;	Tramadol Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
Sneezing; Tenderness;	Zenpep	S	Unknown	Unk Unk,Unk	Not Reported
Thinking Abnormal; Visual	Enbrel	S	Unknown	Unk Unk,Unk	Not Reported
Impairment; Vomiting;	Rituxan	S	Unknown	Unk Unk,Unk	Not Reported
Weight Decreased;	Actemra	S	Unknown	Unk Unk,Unk	Not Reported
Wheezing; Wound	Simponi Aria	S	Unknown	Unk Unk,Unk	Not Reported
	Humira	S	Unknown	Unk Unk,Unk	Not Reported
	Antivert [Meclozine	S	Oral	12.5 Mg,Tid	Not Reported
	Hydrochloride;Nicotinic Acid]				

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Abreva	S		Unk	Not Reported
Cyclosporine	S	Unknown	Unk Unk,Unk	Not Reported
Cetylpyridinium Chloride;Dichlorobenzyl Alcohol;Lidocaine Hydrochlorid	S	Unknown	Unk Unk,Unk	Not Reported
Actifed [Pseudoephedrine Hydrochloride;Triprolidine Hydrochloride]	S		Unk	Not Reported
Vitamin D2	C	Unknown	Unk Unk,Unk	Not Reported
Bactroban [Mupirocin]	C	Unknown	Unk Unk,Unk	Not Reported
Citalopram Hydrobromide	C	Unknown	Unk Unk,Unk	Not Reported
Tamiflu	C	Unknown	Unk Unk,Unk	Not Reported
Tylenol	C	Unknown	Unk Unk,Unk	Not Reported
Singulair	C	Unknown	Unk Unk,Unk	Not Reported
Synthroid	C	Unknown	Unk Unk,Unk	Not Reported
Zoloft	C	Unknown	Unk Unk,Unk	Not Reported
Vitamins Nos	C	Unknown	Unk Unk,Unk	Not Reported
Restasis	C	Unknown	Unk Unk,Unk	Not Reported
Folic Acid	C	Unknown	Unk Unk,Unk	Not Reported
Nasocort	C	Unknown	Unk Unk,Unk	Not Reported
Advair	C	Unknown	Unk Unk,Unk	Not Reported
Prevacid	C	Unknown	Unk Unk,Unk	Not Reported
Flexeril [Cyclobenzaprine Hydrochloride]	C	Unknown	Unk Unk,Unk	Not Reported
Vicodin	C	Unknown	Unk Unk,Unk	Not Reported
Refresh [Carmellose]	C	Unknown	Unk Unk,Unk	Not Reported
Fosamax	C	Unknown	Unk Unk,Unk	Not Reported
Phenergan [Promethazine]	C	Unknown	Unk Unk,Unk	Not Reported
Tazact [Piperacillin Sodium;Tazobactam Sodium]	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	Unk Unk,Unk	Not Reported
Systane	C	Unknown	Unk Unk,Unk	Not Reported

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Zinc	C	Unknown	Unk Unk,Unk	Not Reported
Isopto Tears [Hypromellose]	C	Unknown	Unk Unk,Unk	Not Reported
Mobic	C	Unknown	Unk Unk,Unk	Not Reported
Lamictal	C	Unknown	Unk Unk,Unk	Not Reported
Diamode	C	Unknown	Unk Unk,Unk	Not Reported
Esomeprazole	C	Unknown	Unk Unk,Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk Unk,Unk	Not Reported
Zanaflex	C	Unknown	Unk Unk,Unk	Not Reported
Retin A	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin D3	C	Unknown	Unk Unk,Unk	Not Reported
Hydrocortisone	C	Unknown	Unk Unk,Unk	Not Reported
Zaditor [Ketotifen]	C	Unknown	Unk Unk,Unk	Not Reported
Rubramin	C	Unknown	Unk Unk,Unk	Not Reported
Zantac	C	Unknown	Unk Unk,Unk	Not Reported
Deltasone [Dexamethasone]	C	Unknown	Unk Unk,Unk	Not Reported
Vitamin B12 [Cyanocobalamin]	C	Unknown	Unk Unk,Unk	Not Reported
Protopic	C	Unknown	Unk Unk,Unk	Not Reported
Flu Vaccine Vii	C		Unk	Not Reported
Pneumococcal Vaccine	C		Unk	Not Reported
Norco	C		Unk	Not Reported
Esomeprazole Magnesium	C		Unk	Not Reported
Deltasone [Prednisone]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	13228895	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832720		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Breast Cancer; Condition Aggravated; Contraindicated Product	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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Administered; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Joint Swelling; Loss Of Consciousness; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Arava	S	Unknown	Therapy Duraition: 5 Years	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	14351652	EXPEDITED (15-DAY)		OT	CA-SA-2017SA268415		78 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Grip Strength Decreased; Rheumatoid Arthritis	Hydroxychloroquine			S	Oral	Unk Unk,Unk		Sanofi
	Leflunomide			S	Oral	20 Mg,Qd		Sanofi
	Prednisone			S	Unknown	20 Mg,Unk		Not Reported
	Prednisone			S	Unknown	40 Mg,Qd		Not Reported
	Sulfasalazine			S	Oral	2 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk Unk,Qw		Not Reported
	Methotrexate Sodium			S	Subcutaneous	15 Mg, 1 Every 1 Week		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	14875538	EXPEDITED (15-DAY)		OT	CA-SA-2018SA126619			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Hydroxychloroquine Sulfate			S	Oral	400 Mg,Qd		Sanofi
	Arava			S	Oral	20 Mg,Unk		Sanofi
	Sulfasalazine			S	Unknown	500 Mg		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg,Qd		Sanofi
	Humira			S	Subcutaneous	40 Mg,Qow		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg,Qw		Not Reported
	Orencia			S	Unknown	Unk Unk,Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk Unk,Unk		Not Reported
	Simponi			S	Subcutaneous	Unk Unk,Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	15193064	EXPEDITED (15-DAY)		OT	CA-ROCHE-2159066			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	15268954	EXPEDITED (15-DAY)		HO	CA-ROCHE-2168145			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Viral Infection	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	15275893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2168133			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis; Tuberculin Test Positive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

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Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Amoxil [Amoxicillin]	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C		Not Reported
Leflunomide	C	Unknown	Not Reported
Amoxicillin	C		Not Reported
Trihydrate;Clavulanate			
Potassium			
Adalimumab	C		Not Reported
Bcg	C		Not Reported
Clavulanate Potassium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	15354415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2180456		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	15390537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2185424			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	15705892	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20181205173			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Arthralgia; Cardiac Failure; Cardiac Failure Congestive; Contraindicated Product Administered; Cough; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dyspnoea; Gastric Disorder; Headache; Hepatic Steatosis; Hypertension; Loss Of Employment; Malaise; Multiple Allergies; Nausea; Off Label Use; Product Use Issue; Rash;	Levaquin			S	Unknown			Not Reported
	Avelox			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported
	Keflex			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Losartan			S	Unknown			Not Reported
	Hydralazine Hydrochloride			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cephalexin Monohydrate			S	Unknown			Not Reported
	Cephalexin			S	Unknown			Not Reported
	Enalapril			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapeutic Product Effect Decreased	Enalapril Maleate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Fosamax	S	Unknown	Not Reported
	Hctz	S	Unknown	Not Reported
	Hydrochlorothiazide	S	Unknown	Not Reported
	Isoniazid	S	Unknown	Not Reported
	Losartan Potassium	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Metoprolol Tartrate	S	Unknown	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Pariet	S	Unknown	Not Reported
	Penicillin G /00000902/	S	Unknown	Not Reported
	Penicillin G /00000903/	S	Unknown	Not Reported
	Plaquenil S	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Ciprofloxacin	S	Unknown	Not Reported
	Pantoprazole Magnesium	S	Unknown	Not Reported
	Tecta	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Venofer	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Atenolol	C	Unknown	Not Reported
	Colchicine	C	Unknown	Not Reported
	Coversyl	C	Unknown	Not Reported
	Leucovorin	C	Unknown	Not Reported
	Levothyroxine Sodium	C	Unknown	Not Reported

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Ranitidine			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	16199830	EXPEDITED (15-DAY)		DS, HO, OT	CA-009507513-1904CAN006247		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase; Aspartate Aminotransferase Increased; Asthenia; Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Chills; Condition Aggravated; Contraindicated Product Administered; Contusion; Cough; Deep Vein Thrombosis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Enthesopathy; Erythema; Fall; Fatigue; Gastric Disorder; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin;	Fosamax			S	Unknown	70 Milligram, Qw (1 Every 1 Week)		Merck	
	Fosamax			S	Unknown	70 Milligram, 1 Every 1 Week		Merck	
	Fosamax			S	Unknown	Unk		Merck	
	Fosamax			S	Unknown	70 Milligram, 4 Every 1 Week		Merck	
	Fosamax			S	Unknown	70 Milligram		Merck	
	Actemra			S	Intravenous (not otherwise specified)	360.0 Milligram,Qm (1every 1 Month) (Also Reported As Every 4 Weeks)		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	680.0 Milligram, 1 Every 1 Month(Also Reported As Every 4 Weeks)		Not Reported	
	Actemra			S	Unknown	680.0 Milligram		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	2.68 Milligram, 1 Every 4 Weeks		Not Reported	
	Actemra			S		360 Milligram 1 Every 1 Month; Dosage Form: Not Specified		Not Reported	
	Actemra			S	Unknown	680 Milligram 1 Every 1 Months (Dosage Form: Not Specified)		Not Reported	
	Actemra			S		360.0 Milligram		Not Reported	
	Alendronic Acid			S	Unknown	70 Milligram, Qw (1 Every 1 Week)		Not Reported	
	Alendronic Acid			S	Unknown	70.0 Milligram, 1 Every 1		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Headache; Heart Rate Increased;				Week	
Hypercalcaemia;	Codeine	S	Unknown	Unk	Not Reported
Hypersensitivity; Infection; Inflammation; Influenza;	Enbrel	S	Unknown	25.0 Milligram,Biw (2 Every 1 Week)	Not Reported
Infusion Related Reaction; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Muscular Weakness;	Enbrel	S	Unknown	25 Milligram , (1 Every 2 Weeks)	Not Reported
Musculoskeletal Stiffness;	Enbrel	S	Unknown	50.0 Milligram, Qw(1 Every 1 Week)	Not Reported
Mycotic Allergy; Nausea; Off Label Use; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling;	Enbrel	S	Subcutaneous	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
Product Use Issue; Productive Cough;	Enbrel	S	Unknown	Unk	Not Reported
Psoriatic Arthropathy;	Enbrel	S	Unknown	25.0 Milligram	Not Reported
Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased;	Enbrel	S	Unknown	50.0 Milligram	Not Reported
Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer;	Enbrel	S	Unknown	25 Milligram, 1 Every 1 Weeks	Not Reported
Speech Disorder; Synovitis; Tendonitis; Tenosynovitis;	Humira	S	Subcutaneous	40 Milligram	Not Reported
Therapeutic Product Effect Decreased; Therapeutic Response Decreased;	Humira	S	Subcutaneous	40.0 Milligram,Biw (1 Every 2 Weeks)	Not Reported
Tongue Disorder; Ulcer	Humira	S	Subcutaneous	40 Milligram 11 Every 2 Weeks	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200.0 Milligram, Qd (1 Every 1 Day)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	20.0 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	360 Milligram 1 Every 1 Months	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	680 Milligram	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Leflunomide	S	Oral	Unk	Not Reported
	Leflunomide	S	Oral	20 Milligram	Not Reported
	Leflunomide	S	Unknown	20 Milligram	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	12.0 Milligram, Every 4 Weeks(1every4week)	Not Reported
Methotrexate	S	Unknown	15.0 Milligram, (1every 4week)	Not Reported
Methotrexate	S	Unknown	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	70 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	12 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Subcutaneous	15.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	12 Milligram, (1 Every 1 Weeks)	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Unknown	12 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram, Qw (1 Every 1 Week)	Not Reported

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Methotrexate	S	Subcutaneous	15 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	10 Milligram, (1 Every 4 Weeks)	Not Reported
Methotrexate	S	Unknown	10.0 Milligram	Not Reported
Methotrexate	S	Oral	25 Milligram, Qw (1 Every 1 Week)	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Oral	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	12.5 Milligram	Not Reported
Methotrexate	S	Unknown	15 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Oral	10 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	10.0 Milligram, 1 Every 1 Weeks	Not Reported
Methotrexate	S	Unknown	70 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Parenteral	50 Milligram, Qm (1 Every 1 Month)	Not Reported
Myochrysine	S	Intramuscular	25.0 Milligram, Qw (1 Every 1 Week)	Not Reported
Myochrysine	S	Parenteral	Unk	Not Reported
Myochrysine	S	Intramuscular	50 Milligram, 1 Every 2 Weeks	Not Reported
Myochrysine	S	Intramuscular	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	780.0 Milligram, Qw(1every1week)	Not Reported
Orencia	S	Unknown	760 Milligram, Qw (1 Every 1 Week)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Unknown	780 Mg, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Simponi	S	Unknown	360.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Simponi	S	Subcutaneous	680.0 Milligram, Qm (1 Every 1 Month)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk, Dosage Form Reported As Powder For Solution Intravenous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 365.0 (Units Not Provided)	Not Reported
Rituxan	S	Intravenous drip	1000 Milligram, 2 Every1 Day	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	1000.0 Milligram (2 Every 1 Day)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000.0 Milligram (1 Every 12hour(S))	Not Reported
Sulfasalazine	S	Unknown	500 Milligram, Dosage Form Reported As Not Specified	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, 1 Every 1 Weeks (Therapy Duration: 366 (Units Not Provided))	Not Reported
Sulfasalazine	S	Endocervical	Unk	Not Reported
Sulfasalazine	S	Unknown	780 Milligram, Qw	Not Reported
Sulfasalazine	S	Endocervical	Unk, Dosage Form Reported As Not Specified	Not Reported
Arava	S	Unknown	Unk	Not Reported

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Cimzia	S	Subcutaneous	Unk, Single-Use Pre-Filled Syringe, Dosage Form Reported As Solution Subcutaneous	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Apo Hydroxyquine	S	Unknown	Unk	Not Reported
Tocilizumab	S	Unknown	680 Milligram, 1 Every 4 Weeks	Not Reported
Tocilizumab	S	Unknown	380 Milligram	Not Reported
Tocilizumab	S	Unknown	360 Milligram, 1 Every 1 Months	Not Reported
Etanercept	S	Unknown	25 Milligram 1 Every 1 Wek	Not Reported
Etanercept	S	Unknown	25.0 Milligram 2 Every 1 Wek	Not Reported
Etanercept	S	Unknown	50 Milligram 1 Every 1 Wek	Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S			Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qm	Not Reported
Cosentyx	S	Subcutaneous	300 Milligram, Qm	Not Reported
Ergocalciferol	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole	S	Unknown	Dosage Form: Not Specified	Not Reported
Apo Ibuprofen	S	Oral	Unk	Not Reported
Apo Ibuprofen	S			Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	60 Milligram 2 Every 1 Days	Not Reported
Apremilast	S	Unknown	Unk	Not Reported
Apremilast	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apremilast	S	Unknown	60 Milligram	Not Reported
Ibuprofen	S		600 Milligram; Dosage Form: Not Specified	Not Reported
Ibuprofen	S	Oral	600 Milligram 1 Every 1 Days	Not Reported
Ibuprofen	S	Oral	Unk, Qd	Not Reported
Stelara	S	Subcutaneous	Unk, Dosage Form Reported As Solution Subcutaneous	Not Reported
Stelara	S	Subcutaneous	Unk	Not Reported
Otezla	S	Unknown		Not Reported
Rituximab	S			Not Reported
Cyclosporine	S	Unknown	150.0 Milligram, Q24h (1every24hours) (1 Every 1 Day)	Not Reported
Cyclosporine	S	Unknown	Unk	Not Reported
Cyclosporine	S	Unknown	150.0 Milligram,1 Every 24 Hours	Not Reported
Motrin (Ibuprofen)	S		600 Milligram, Qd	Not Reported
Motrin (Ibuprofen)	S		600 Milligram, Qd	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Q24h(1every24 Hours) (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	10 Milligram, Q2h (1 Every 2 Hours)	Not Reported
Prednisone	C	Unknown	10.0 Milligram	Not Reported
Prednisone	C	Unknown	20.0 Milligram	Not Reported
Prednisone	C	Unknown	10.0 Milligram, Qd (1 Every 1 Day)	Not Reported
Prednisone	C	Unknown	Dosage Form: Not Specified	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	5.0 Milligram, Bid (2 Every	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	C	Oral	1 Day) 5.0 Milligram, Bid (2 Every 1 Day)	Not Reported
Prednisolone	C	Unknown	Unk	Not Reported
Prednisolone	C	Unknown	10.0 Milligram 1 Every 1 Days	Not Reported
Fosamax	C	Unknown	70 Milligram 1 Every 1 Week	Merck
Hydroxychloroquine Sulfate	C	Oral	Unk, 1 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	C	Oral	200 Gram, 2 Every 1 Days	Not Reported
Hydroxychloroquine Sulfate	C	Oral	200 Gram, 2 Every 1 Days	Not Reported
Naproxen	C	Unknown	Dosage Form: Not Specified	Not Reported
Plaquenil	C	Unknown		Not Reported
Simponi	C	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Sulfasalazine	C	Unknown	Dosage Form: Not Specified	Not Reported
Symbicort	C	Unknown		Not Reported
Tramadol Hydrochloride	C	Unknown		Not Reported
Benadryl	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Benadryl	C	Unknown	Unk	Not Reported
Colchicine	C	Oral	Unk	Not Reported
Dexilant	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Febuxostat	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk, Dosage Form Reported As Not Specified	Not Reported
Gravol (Dimenhydrinate)	C	Unknown	Unk	Not Reported
Mogadon	C	Oral	5 Milligram	Not Reported

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Nitrazepam	C	Unknown	5 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Uloric	C	Unknown	80 Milligram Two Every 1 Days	Not Reported
Uloric	C	Unknown	80 Unk	Not Reported
Cyclosporine	C	Unknown	Dosage Form Not Specified	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	16823349	EXPEDITED (15-DAY)		OT	CA-SAKK-2019SA185374AA		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Sarilumab			S				Sanofi
Alopecia; Anti-Cyclic	Cortisone Acetate			S				Not Reported
Citrullinated Peptide	Desoximetasone			S				Sanofi
Antibody Positive;	Diclofenac Sodium			S				Not Reported
Arthropathy; Blister;	Topicort			S	Cutaneous			Sanofi
Contraindicated Product	Hydroxychloroquine Sulfate			S				Sanofi
Administered; Discomfort;	Prednisone			S		Unk		Not Reported
Drug Ineffective; Drug	Arava			S	Oral	Unk		Sanofi
Intolerance; Exposure	Cetirizine Hydrochloride			S				Not Reported
During Pregnancy;	Cetirizine			S				Not Reported
Fatigue; General Physical	Hydrochloride/Pseudoephedrine							
Health Deterioration;	Hydrochloride							
Glossodynia; Hand	Desoximetasone			S	Oral			Sanofi
Deformity; Hepatic	Alendronate Sodium			S	Oral			Not Reported
Enzyme Increased; Hip	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
Arthroplasty;	Hydroxychloroquine Sulfate			S		1 Df, Qd		Sanofi
Hypersensitivity; Infusion	Leflunomide			S	Oral			Sanofi
Related Reaction; Joint	Methotrexate			S		Unk		Not Reported
Swelling; Knee	Methotrexate			S	Oral	Unk		Not Reported
Arthroplasty; Live Birth;	Methotrexate			S	Oral	1 Df, Qd		Not Reported
Pain; Pemphigus;								
Pericarditis; Product Use								
Issue; Rash; Rheumatoid								
Arthritis; Rheumatoid								
Factor Positive; Swelling;								

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Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Plaquenil	S	Oral	1 Df, Qd	Sanofi
	Prednisone	S			Not Reported
	Pseudoephedrine Hydrochloride	S			Sanofi
	Paracetamol	S			Not Reported
	Cetirizine Hydrochloride	S			Not Reported
	Hydrocortisone Acetate	S	Subcutaneous		Sanofi
	Folic Acid	S			Not Reported
	Stelara	S			Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Methotrexate Sodium	S	Oral		Not Reported
	Golimumab	S			Not Reported
	Cimzia	S	Subcutaneous	Unk, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Hydroxychloroquine	S	Oral	1 Df, Qd	Not Reported
	Actemra	S			Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Atasol [Paracetamol]	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	16849610	EXPEDITED (15-DAY)		OT	CA-ROCHE-2411011		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension;	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Azathioprine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Off Label Use; Pneumonia	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified) Powder For Solution Intravenou	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17233191	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508660		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nephrolithiasis; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 823.0		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Oral	Therapy Duration:	Not Reported
Orencia	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 6.0 Months	Not Reported
Tylenol	S	Unknown		Not Reported
Acetaminophen;Diphenhydramine Hydrochloride	S	Unknown		Not Reported
Celebrex	C	Unknown		Not Reported
Hydromorphone Hydrochloride	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Tylenol W/Codeine No. 3	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17250742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514001		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Failure	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Arava	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17299256	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524986		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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Detailed Report

Xeljanz Xr	C		Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17333671	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530860		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Joint Swelling; Off Label Use; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single-Use, Preservative-Free Prefilled Syringes		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
Prednisone			C				Not Reported	
Desoximetasone			C				Not Reported	
Methotrexate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17358367	EXPEDITED (15-DAY)		HO	CA-ROCHE-2530347		75 YR	Female	CAN



Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Adverse Reaction;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthralgia; Arthropathy; Blood Creatinine	Apo-Gabapentin			S	Unknown			Not Reported
Increased; Blood	Arava			S	Oral			Not Reported
Magnesium Increased; Blood Potassium	Celebrex			S	Oral			Not Reported
Increased; Bone Cyst; Contraindicated Product	Celecoxib			S	Oral			Not Reported
Administered; Crohn'S Disease; Cyst; Deafness	Celecoxib			S				Not Reported
Neurosensory; Deformity; Diarrhoea; Drug	Enbrel			S	Subcutaneous			Not Reported
Hypersensitivity; Drug Ineffective; Drug	Fentanyl Matrix			S	Unknown			Not Reported
Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue;	Gabapentin			S	Oral			Not Reported
Gastrointestinal Disorder; Hospitalisation;	Hydroxychloroquine			S	Unknown			Not Reported
Hypersensitivity; Infection; Joint Swelling; Mobility Decreased;	Methotrexate			S	Subcutaneous			Not Reported
Musculoskeletal Stiffness; Myocardial Infarction;	Myochrysine			S	Intramuscular			Not Reported
Nausea; Osteoarthritis; Osteopenia;	Nortriptyline			S	Unknown			Not Reported
Osteosclerosis; Pain; Pain In Extremity; Pleural Fibrosis; Pleural	Orencia			S	Subcutaneous			Not Reported
Thickening; Presbycusis; Renal Impairment;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Rheumatoid Arthritis; Skin Lesion; Sleep Disorder;	Oxycontin			S	Unknown			Not Reported
Therapeutic Product Effect Decreased; Treatment Failure	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Nasonex			C	Unknown			Not Reported
	Aclasta			C	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported
	Ascorbic Acid			C				Not Reported
	Biotin			C				Not Reported
	Calcium			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported

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Esomeprazole	C		Not Reported
Fentanyl	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Fish Oil	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C		Not Reported
Loperamide	C		Not Reported
Esomeprazole	C		Not Reported
Nortriptyline	C	Unknown	Not Reported
Omega 3 [Docosahexaenoic Acid;Eicosapentaenoic Acid]	C		Not Reported
Omega 3-6-9 [Fish Oil]	C	Unknown	Not Reported
Oxycodone Terephthalate	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Prednisone	C		Not Reported
Pyridoxine	C		Not Reported
Sodium	C		Not Reported
Thiamine Hcl	C		Not Reported
Trazodone	C		Not Reported
Tylenol	C		Not Reported
Vitamin A [Retinol]	C		Not Reported
Vitamin B3	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17425017	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0812		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular	Kineret			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17433128	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0819		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Kineret			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S		Not Reported
Imuran	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17443585	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552671		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Vaccine; Condition Aggravated; Diarrhoea; Drug Ineffective; Fall; Hypersensitivity; Laryngeal Disorder; Nausea; Product Use Issue; Pruritus; Rheumatoid Arthritis; Treatment Failure; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Varicella Zoster Vaccine Live			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17580328	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0808		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Contraindicated Product	Kineret	S	Unknown	Not Reported
Administered; Drug	Arava	S	Unknown	Not Reported
Ineffective; No Adverse	Cimzia	S	Unknown	Not Reported
Event; Prescribed	Cimzia	S	Subcutaneous	Not Reported
Underdose; Rheumatoid	Dextromethorphan	S	Unknown	Not Reported
Arthritis; Therapeutic	Hydrobromide	S		
Product Effect Incomplete;	Eletriptan Hydrobromide	S		Not Reported
Treatment Failure	Eletriptan Hydrobromide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	0.75 Mg Once Monthly Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz Xr	S	Unknown	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	1 Every 1 Month Not Reported
	Apo-Azathioprine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Apo-Leflunomide	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Azathioprine	S		Not Reported
	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Etanercept	S	Subcutaneous	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Calcium	C	Oral	Not Reported
Dilaudid	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Hydromorph Contin	C	Unknown	Not Reported
Hydromorph Contin	C	Unknown	Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Apo-Gabapentin	C	Unknown	Not Reported
Atorvastatin Calcium	C	Oral	Not Reported
Atorvastatin Calcium	C	Oral	Not Reported
Cipralex	C	Unknown	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Escitalopram	C	Unknown	Not Reported

Dose: 0.625 Mg

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Estrace	C	Unknown	Dose: 0.5 Mg	Not Reported
Gabapentin	C	Oral		Not Reported
Gabapentin	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown	Dose: 12.5 Mg	Not Reported
Hydromorphone Hcl	C	Oral		Not Reported
Hydromorphone Hcl	C	Oral		Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc	C	Unknown		Not Reported
Shark Liver Oil	C	Unknown		Not Reported
Tapentadol Hydrochloride	C	Unknown		Not Reported
Taro-Mupirocin	C	Topical		Not Reported
Tramacet	C	Oral		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported
Vitamin D	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17696997	EXPEDITED (15-DAY)		HO, OT	BE-ADVANSZ PHARMA-202004003502			Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Off Label Use; Rhabdomyolysis	Hydroxychloroquine			S	Oral	400 Mg, Bid, Film-Coated Tablet		Concordia	
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Film-Coated Tablet		Concordia	
	Haldol			C		Unk		Not Reported	
	Paracetamol			C		1 Unk		Not Reported	
	Fraxiparine			C		Unk		Not Reported	
	Dafalgan Forte			C		1 G		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine

C

10 Mg/ML

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17701011	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-244837		75 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Levofloxacin			S	Unknown	Unk		Ranbaxy
	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxiclороquina Sulfato (2143su)			S	Oral	200 Milligram, Daily		Not Reported
	Hidroxiclороquina Sulfato (2143su)			S				Not Reported
	Lopinavir+Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Tacrolimus (2694a)			S	Oral	Unk		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Milligram, Daily		Not Reported
	Prednisona (886a)			C	Oral	20 Milligram, Daily		Not Reported
	Ceftriaxona (501a)			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17718685	EXPEDITED (15-DAY)		DS, OT	CA-COLGATE PALMOLIVE COMPANY- 20200400745			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Chlorhexidine Unspecified			S	Unknown			Colgate
Alopecia; Anti-Cyclic	Periogard Alcohol Free Rinse			S	Buccal	Alcohol Free		Colgate
Citrullinated Peptide	Chlorhexidine Gluconate			S	Unknown	Oral Rinse		Colgate
Antibody Positive;	Unspecified			S				Not Reported
Arthralgia; Arthropathy;	Oxycodone			S	Intravenous (not otherwise specified)	3011.2 Milligram		Not Reported
Blister; Confusional State;	Actemra			S				Not Reported
Contraindicated Product								
Administered; Contusion;	Actemra			S	Subcutaneous	Unk		Not Reported
Discomfort; Drug								
Ineffective; Drug								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Duodenal Ulcer Perforation;	Actemra	S	Intravenous (not otherwise specified)	752.8 Milligram	Not Reported
Dyspnoea; Fatigue;	Actemra	S	Intravenous (not otherwise specified)	2912 Milligram	Not Reported
Folliculitis; Gastrointestinal Disorder; Glossodynia;	Actemra	S	Intravenous (not otherwise specified)	728 Milligram	Not Reported
Hand Deformity;	Apo-Prednisone	S	Oral		Not Reported
Helicobacter Infection;	Desoximetasone	S	Oral		Not Reported
Hepatic Enzyme Increased;	Enbrel	S	Subcutaneous	Unk	Not Reported
Hypersensitivity; Ill-Defined Disorder;	Enbrel	S	Subcutaneous	Unk	Not Reported
Impaired Healing;	Methotrexate	S	Oral	20 Milligram 1 Day	Not Reported
Infection; Infusion Related Reaction; Irritable Bowel Syndrome; Joint Swelling;	Methotrexate	S	Oral	25 Milligram	Not Reported
Lower Respiratory Tract Infection; Muscle Injury;	Methotrexate	S	Oral	20 Milligram 1 Week	Not Reported
Nasopharyngitis; Pain;	Humira	S	Subcutaneous	40 Milligram	Not Reported
Pemphigus; Pericarditis;	Acetaminophen	S	Unknown		Not Reported
Peripheral Swelling;	Cortisone	S	Topical	25 Milligram	Not Reported
Pregnancy; Pruritus;	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Pyrexia; Rash;	Sulfasalazine	S	Oral	500 Milligram	Not Reported
Rheumatoid Arthritis;	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
Sinusitis; Sleep Disorder	Phthalylsulfathiazole	S	Oral	500 Milligram	Not Reported
Due To General Medical Condition, Insomnia Type;	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Stomatitis; Swelling;	Phthalylsulfathiazole	S	Oral	2000 Milligram	Not Reported
Synovitis; Systemic Lupus Erythematosus;	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Therapeutic Product Effect Decreased; Weight Increased; Wound	Remicade	S	Intravenous (not otherwise specified)	500 Milligram, Cyclical	Not Reported
	Oxycodone Terephthalate	S			Not Reported
	Sulfamethoxazole	S			Not Reported
	Fosamax	S	Oral		Not Reported
	Oxycodone;Paracetamol	S	Unknown		Not Reported
	Folic Acid	S	Unknown	5 Milligram	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Unknown	1 Milligram	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Cetirizine	S	Unknown	10 Milligram	Not Reported
Prednisone	S	Oral	7.5 Milligram	Not Reported
Diclofenac	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	400 Milligram	Not Reported
Cimzia	S	Subcutaneous		Not Reported
Hydroxychloroquine	S	Oral	400 Milligram	Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Tofacitinib Citrate	S	Unknown	10 Milligram	Not Reported
Sulfamethoxazole And Trimethoprim	S			Not Reported
Arava	S	Oral	20 Milligram	Not Reported
Chloraprep	S		Topical	Not Reported
Topicort [Hydrocortisone Acetate]	S	Cutaneous		Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	10 Milligram	Not Reported
Leflunomide	S	Oral		Not Reported
Oxycodone Hydrochloride	S			Not Reported
Tofacitinib	S	Unknown	10 Milligram	Not Reported
Reactine [Cetirizine Hydrochloride]	C			Not Reported
Salazopyrin	C	Unknown		Not Reported
Pantoprazole Sodium	C			Not Reported
Pantoloc [Pantoprazole]	C			Not Reported
Cetirizine Dihydrochloride	C			Not Reported
Paracetamol/Codeine	C			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atasol [Paracetamol]	C	Unknown	Not Reported
Tylenol With Codeine	C		Not Reported
Tylenol [Paracetamol]	C		Not Reported
Desogestrel And Ethinylestradiol	C		Not Reported
Ibuprofen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17750410	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1230308		26 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Psychosis; Suicide Attempt	Hidroxiclорокина (2143a)			S	Oral	400 Milligram Daily;		Teva
	Alopurinol 100 Mg Comprimido			C	Oral	100 Mg		Not Reported
	Paracetamol (12a)			C	Oral	1 Gram 8 Hours		Not Reported
	Famotidina 20 Mg Comprimido			C	Oral	20 Mg		Not Reported
	Doxazosina (2387a)			C	Oral	4 Mg		Not Reported
	Ceftriaxona 2.000 Mg Inyectable Iv			C	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Cefixima (2400a)			C	Oral	200 Mg 12 Hours		Not Reported
	Magnogene 53 Mg Comprimidos Recubiertos			C	Oral	106 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Prednisona (886a)			C		5 Mg		Not Reported
	Prednisona (886a)			C	Oral	20 Mg		Not Reported
	Carvedilol 25 Mg Comprimido			C	Oral	25 Mg		Not Reported
	Zemplar 1 Microgramo Capsulas Blandas			C	Oral	1 Microgram		Not Reported
	Myfortic 360 Mg Comprimidos Gastrorresistentes			C	Oral	360mg 12 Hours		Not Reported
	Enoxaparina Sodio 20 Mg (2.000 Ui) Inyectable 0,2 Ml			C	Subcutaneous	20 Mg		Not Reported
	Fosrenol			C	Oral	750 Mg 12 Hours		Not Reported
	Metamizol 575 Mg Capsula			C	Oral	575 Mg		Not Reported
	Tacrolimus (2694a)			C	Oral	2 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tacrolimus (2694a)	C	Oral	2 Mg	Not Reported
Tacrolimus (2694a)	C	Oral	1 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17765762	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200437414		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Desoximetasone			C				Not Reported
	Methotrexate			C	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17767549	EXPEDITED (15-DAY)		HO	FI-BAUSCH-BL-2020-013895			Unknown	FIN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia; Pneumonia Streptococcal	Prednisolone			S	Unknown	2 Subjects; Combination With Mtx, And Bdmard; Combination With Mtx, And Certolizumab (Third		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisolone	S	Unknown	Bdmard) One Subject; Combination With Leflunomide, And Hydroxychloroquine	Not Reported
Methotrexate	S	Unknown	Two Subjects	Not Reported
Methotrexate	S			Not Reported
Leflunomide	S	Unknown	One Subject	Not Reported
Hydroxychloroquine	S	Unknown	One Subject	Not Reported
Certolizumab	S	Unknown	Third Bdmard; One Subject	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17801320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2595664		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Cataract Operation; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	S	Oral		Not Reported
Xeljanz	S	Oral	2.0 Years	Not Reported
Xeljanz	S	Oral		Not Reported
Prednisone	C	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Acetaminophen	C	Unknown		Not Reported
Codeine	C	Unknown		Not Reported
Arava	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17804850	EXPEDITED (15-DAY)		HO	IT-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-037471		89 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug Level Increased; Drug Interaction	Apixaban			S	Oral	2.5 Milligram, Bid		Bristol Myers Squibb
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17804885	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2602052		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17804897	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1236797		24 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva	
	Lopinavir/Ritonavir Sandoz 200 Mg/50 Mg Comprimidos Recubiertos Con Pe			S	Oral	4 Dosage Forms Daily; 200 Mg / 50 Mg		Not Reported	
	Interferon Beta-1b (2305od)			S	Subcutaneous	0.25 Mg		Not Reported	
	Cloroquina [Chloroquine]			S	Oral	310 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17804903	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600819		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Subcutaneous	Single Use Solution		Not Reported	
	Enbrel			S	Unknown	1.0 Dosage Forms		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Not Reported
Arava	C	Unknown	Not Reported
Codeine Phosphate	C	Unknown	Not Reported
Lyrica	C	Oral	Not Reported
Tylenol	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17804959	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599174		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S				Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Neoral			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neoral	S	Oral	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Single Use Prefilled Syringe Not Reported
Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598757			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C				Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805206	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598696		63 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805222	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598386		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Aspirin [Acetylsalicylic Acid]	C		Not Reported
Cymbalta	C		Not Reported
Hydromorphone	C		Not Reported
Synthroid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805262	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 2062		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fall; Gait Inability; Malaise; Paralysis; Spinal Fracture	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805480	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598565		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

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	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Unknown	Not Reported
	Risedronic Acid	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805682	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599992			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diverticulitis; Drug Ineffective; Pulmonary Toxicity	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805708	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202004004352			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use	Hydroxychloroquine			S		Unk		Concordia

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dupixent			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601279			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported	
	Doxycycline			S	Unknown			Not Reported	
	Doxycycline Hyclate			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805795	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247183		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cornea Verticillata	Hydroxychloroquine			S	Unknown	600 Milligram, Bid		Sun	
	Hydroxychloroquine			S	Unknown	1200 Milligram		Sun	
	Everolimus			C	Unknown	10 Milligram, Qd		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805801	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598742		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthrodesis; Condition Aggravated; Cough; Drug Ineffective; Headache; Rheumatoid Arthritis; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805865	EXPEDITED (15-DAY)		HO, OT	CH-IPCA LABORATORIES LIMITED-IPC-2020-CH- 001562			Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Haemolysis; Off Label Use	Amoxicillin & Clavulanate			S	Unknown	1.2 Gram, Qid		Not Reported
	Potassium Hydroxychloroquine			S	Unknown	600 Milligram, Single		Ipca
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805867	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602952			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; Drug Ineffective; Rheumatoid Arthritis;	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weight Increased	Etanercept	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805896	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598821			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Drug Ineffective; Finger Deformity; Joint Swelling; Off Label Use; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Naproxen			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17805934	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598728		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra	S	Subcutaneous	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806026	EXPEDITED (15-DAY)		DE	FR-ABBVIE-20K-056- 3408720-00		76 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Coronavirus Infection; Septic Shock	Kaletra 200/50			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598842		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	otherwise specified)	Not Reported
Acetylsalicylic Acid	C	Intravenous (not otherwise specified)	Not Reported
Insulin	C	Oral	Not Reported
Lantus	C	Subcutaneous	Not Reported
Lozide [Indapamide]	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Prednisone	C		Not Reported
Ramipril	C		Not Reported
Naproxen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806054	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598554			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Factor Positive; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806078	EXPEDITED (15-DAY)		HO	ES-ACCORD-182452		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Enoxaparin			S	Subcutaneous	60 Mg Cada 12 Horas		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexamethasone	S	Intravenous (not otherwise specified)	20 Mg Daily For 6 Days Followed By 10 Mg Daily X 5 Days	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806221	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598032		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Joint Swelling; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Amitriptyline Hydrochloride			C	Unknown			Not Reported
	Arava			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Hydrochlorothiazide			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Premarin			C	Unknown			Not Reported
	Sumatriptan Succinate			C	Unknown			Not Reported
	Tenormin			C	Unknown			Not Reported
	Tofacitinib			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806227	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236784			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Methotrexate Sodium			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Topical			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Phthalylsulphathiazole			S	Unknown			Not Reported	
	Prednisone			S	Intravenous (not otherwise specified)			Not Reported	
	Reactine (Cetirizine Hydrochloride)			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806260	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598086		52 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Hypersensitivity; Joint Range Of Motion Decreased; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Off Label Use; Peripheral Swelling; Rash; Tendon Disorder	Actemra			S	Unknown			Not Reported	
	Bactrim			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Hydroxychloroquine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806262	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-014818			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole			S	Unknown			Not Reported	
	Erythromycin			S	Unknown			Bausch And Lomb	
	Erythromycin			S	Unknown			Bausch And Lomb	
	Demerol			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Bisoprolol			S	Unknown			Not Reported	
	Erythromycin Base			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Norfloxacin			S	Unknown			Not Reported	
	Plaquenil			S	Oral			Not Reported	

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Levofloxacin	S	Unknown	Not Reported
Arthrotec	S	Unknown	Not Reported
Arthrotec	S		Not Reported
Ceclor	S	Unknown	Not Reported
Celebrex	S	Oral	Not Reported
Humira	S	Subcutaneous	Not Reported
Lyrica	S	Unknown	Not Reported
Meperidine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806269	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600489		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Dysphonia; Dyspnoea; Intentional Product Use Issue; Odynophagia; Off Label Use; Rheumatoid Arthritis; Stridor	Rituximab			S	Unknown			Not Reported	
	Golimumab			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806334	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598098		53 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Disability; Drug Ineffective; Dyspnoea; Impaired Work Ability; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility	Actemra			S	Intravenous (not otherwise specified)	Not Specified		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	

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Decreased; Musculoskeletal Stiffness; Pain; Peripheral Swelling; Physical Disability; Rash; Skin Mass; Therapeutic Product Effect Decreased; Therapy Non-Responder	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ergocalciferol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806352	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598841		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy;	Actemra			S	Unknown			Not Reported
Cerebrovascular Accident;	Apo-Leflunomide			S	Unknown			Not Reported
Drug Ineffective; Eye	Cimzia			S	Subcutaneous			Not Reported
Disorder; Gait Inability;	Enbrel			S	Unknown			Not Reported
Headache; Herpes Zoster;	Humira			S	Subcutaneous			Not Reported
Joint Swelling; Off Label	Hydroxychloroquine			S	Unknown			Not Reported
Use; Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Wheelchair User								

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	Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Aspirin [Acetylsalicylic Acid]	C		Not Reported
	Folic Acid	C		Not Reported
	Methotrexate	C		Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806362	EXPEDITED (15-DAY)		DE, OT	US-ADVANTZ PHARMA-202005005325			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use	Hydroxychloroquine			S		Unk		Concordia	
	Zpac			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806482	EXPEDITED (15-DAY)		OT	ES-ACCORD-182526		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Sulpiride			S	Oral	50 Mg Every 8 Hours		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Mg Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806634	EXPEDITED (15-DAY)		HO	ES-ACCORD-182639		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage; Off Label	Hydroxychloroquine			S	Oral	400 Mg		Not Reported	

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Use; Vessel Puncture Site Haemorrhage	Enoxaparin	S	Subcutaneous	40 Mg	Not Reported
	Dexamethasone	S	Intravenous (not otherwise specified)	20 Mg Dia	Not Reported
	Lysine Acetylsalicylate	S	Intravenous (not otherwise specified)	200 Mg	Not Reported
	Adiro	S	Oral	1 Cp Day, 100 Mg Gastro- Resistant Tablets Efg, 500 Tablets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806646	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1237680		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rash Pruritic	Levofloxacin (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva	
	Hidroxycloquina Sulfato (2143su)			S	Oral	200 Mg		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806764	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598504			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Off Label Use; Pulmonary Toxicity; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not			Not Reported	

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Celebrex		C		otherwise specified) Unknown		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807048	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599975		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Ciclosporin			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Neoral			S	Subcutaneous			Not Reported	
	Neoral			S	Oral			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Xeljanz			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807119	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599986			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599020		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock; Drug Ineffective; Fibromyalgia; Hepatitis; Myocardial Infarction; Off Label Use; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported

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Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone Acetate	C	Unknown	Not Reported
Acetaminophen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807174	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598813		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807176	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598589			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Gait Disturbance; Myocardial Infarction; Pain; Swelling; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported	
	Codeine Sulfate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Leflunomide			C	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807183	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598569		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Drug Ineffective; Intestinal Perforation	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Unknown			Not Reported	
	Adalimumab			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
Sulfasalazine			S	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598518			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Intentional Product Use Issue; Off Label Use; Pneumonia	Actemra			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807193	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247372		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported	
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported	
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807204	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598566			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Female; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Meloxicam	C		Not Reported
Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807237	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598649			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthritis; Blood Cholesterol Increased; Drug Ineffective; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Soft Tissue Disorder; Synovitis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Anakinra			C	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Ativan			C	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Darifenacin			C	Unknown			Not Reported

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Darifenacin Hydrobromide	C		Not Reported
Desoximetason	C		Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Hydromorphone	C	Unknown	Not Reported
Kadian	C	Unknown	Not Reported
Loperamide	C		Not Reported
Morphine Sulfate	C		Not Reported
Vagifem	C		Not Reported
Urispas	C		Not Reported
Trimethoprim	C		Not Reported
Synthroid	C		Not Reported
Omnaris	C		Not Reported
Oxyneo	C		Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Restasis	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807245	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598520		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia;	Actemra			S	Unknown			Not Reported
Arthritis; Blood Cholesterol	Arava			S	Oral			Not Reported
Increased; C-Reactive	Enbrel			S	Unknown			Not Reported
Protein Abnormal; Drug	Humira			S	Subcutaneous			Not Reported
Ineffective; Drug	Humira			S	Unknown			Not Reported
Intolerance; Fibromyalgia;	Humira			S	Unknown			Not Reported
Herpes Zoster; Infection;	Humira			S	Unknown			Not Reported
Joint Swelling;	Remicade			S	Intravenous (not			Not Reported
Leukopenia; Liver					otherwise specified)			
Function Test Abnormal;	Sodium Aurothiomalate			S	Intramuscular			Not Reported
Off Label Use; Oral Pain;	Xeljanz			S	Unknown			Not Reported
Peripheral Swelling;	Xeljanz			S	Unknown			Not Reported
Pneumonia Viral; Soft	Hydroxychloroquine			S	Unknown			Not Reported
Tissue Disorder;	Hydroxychloroquine			S	Unknown			Not Reported
Stomatitis; Swelling;	Hydroxychloroquine			S	Unknown			Not Reported

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Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Anakinra	C		Not Reported
	Ativan	C		Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
	Codeine	C		Not Reported
	Darifenacin	C		Not Reported
	Darifenacin Hydrobromide	C		Not Reported
	Desoximetasone	C		Not Reported
	Dilaudid	C		Not Reported
	Diphenhydramine Hydrochloride	C		Not Reported
	Furosemide	C		Not Reported
	Hydromorphone	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Pantoprazole	C		Not Reported
	Restasis	C		Not Reported
	Rituximab	C	Intravenous drip	Not Reported
	Synthroid	C		Not Reported
	Trimethoprim	C		Not Reported
	Urispas	C		Not Reported
	Vagifem	C		Not Reported
	Kadian	C		Not Reported
	Kenalog [Triamcinolone Acetonide]	C		Not Reported
	Lasix [Furosemide]	C		Not Reported
	Loperamide	C		Not Reported
	Morphine Sulfate	C		Not Reported
	Norflex [Orphenadrine Citrate]	C		Not Reported
	Omnaris	C		Not Reported
	Oxyneo	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807267	EXPEDITED (15-DAY)		DE, HO	FR-TEVA-2020-FR-1237207		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

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Electrocardiogram Qt	Nebivolol	S	Oral	5 Mg	Actavis
Prolonged; Ventricular	Plaquenil	S	Oral	600 Mg	Not Reported
Extrasystoles	Valsartan	C	Oral	160 Mg	Not Reported
	Augmentin	C	Oral	3 Gm	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807315	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597899		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug	Actemra			S	Unknown			Not Reported
Ineffective; Drug	Rituximab			S	Intravenous (not			Not Reported
Intolerance; Fatigue; Hand					otherwise specified)			
Deformity; Headache;	Apo-Leflunomide			S	Unknown			Not Reported
Irritable Bowel Syndrome;	Arava			S	Unknown			Not Reported
Joint Swelling; Loss Of	Cimzia			S	Subcutaneous			Not Reported
Personal Independence In	Enbrel			S	Unknown			Not Reported
Daily Activities; Malaise;	Humira			S	Subcutaneous			Not Reported
Nausea; Off Label Use;	Hydroxychloroquine			S	Unknown			Not Reported
Pain In Extremity;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Peripheral Swelling;	Leflunomide			S	Unknown			Not Reported
Rheumatoid Arthritis;	Methotrexate			S	Unknown			Not Reported
Stress; Therapeutic	Orencia			S	Unknown			Not Reported
Product Effect Incomplete	Remicade			S	Intravenous (not			Not Reported
					otherwise specified)			
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598571		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Angioedema; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Injection Site Pruritus; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Pain; Pneumonia; Pruritus; Pulmonary Fibrosis; Rheumatoid Arthritis; Septic Shock; Synovitis; Treatment Failure; Urinary Tract Infection; Urosepsis	Actemra Rituximab Methotrexate Methyl Salicylate Orencia Remicade Salicylates Nos Sulfasalazine Apo-Leflunomide Azathioprine Enbrel Hydroxychloroquine Hydroxychloroquine Sulfate Leflunomide Humira	S S S S S S S S S S S S S S S	Unknown Intravenous (not otherwise specified) Unknown Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown Unknown Subcutaneous	Therapy Duration: 6.0 Months	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807382	EXPEDITED (15-DAY)		HO	ES-ACCORD-182384		71 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807416	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598837		57 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Gait Disturbance; Inflammation; Mouth Ulceration; Pain; Peripheral Swelling; Rotator Cuff Syndrome; Swelling; Therapeutic Product Effect Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Indometacin			C				Not Reported
	Prednisone			C				Not Reported
	Tramadol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807426	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598036			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807451	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1019154		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Bone Erosion; Diarrhoea; Drug Ineffective; Joint Swelling; Migraine; No Adverse Event; Peripheral Swelling; Prescribed Underdose; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown	7 Milligram Daily;		Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Remicade			S	Unknown	7 Milligram Daily;		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Rituxan			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Prednisone			S	Unknown	7 Milligram Daily;		Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Oral	10 Milligram Daily;		Not Reported	
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported	

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Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Acetaminophen/Codeine Phosphate	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Altace	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Apo-Gabapentin	C	Oral		Not Reported
Apo-Gabapentin	C	Unknown		Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram Daily;	Not Reported
Atorvastatin Calcium	C	Unknown		Not Reported
Ciprallex [Escitalopram]	C	Unknown		Not Reported
Citalopram Hydrobromide	C	Unknown		Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown	120 Milligram Daily;	Not Reported
Cymbalta	C	Unknown		Not Reported
Escitalopram	C	Unknown		Not Reported
Estrace	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Hydromorphone Hcl	C	Oral	6 Milligram Daily;	Not Reported
Mupirocin	C	Topical		Not Reported
Mupirocin	C	Topical		Not Reported
Pantoloc [Pantoprazole]	C			Not Reported
Tapentadol Hydrochloride	C	Unknown		Not Reported
Tramadol Hydrochloride	C	Oral		Not Reported
Tramacet	C	Oral		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807497	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598405		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Butterfly Rash; Condition Aggravated; Drug Ineffective; Epicondylitis; Malaise; Musculoskeletal Pain; Off Label Use; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807531	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598745		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Methotrexate	C		Not Reported
Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598164			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Pseudoephedrine Hcl			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807575	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236739			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematousus	Prednisone			S	Unknown			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807725	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236726			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Arava			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythematousus	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Tocilizumab	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807727	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20200503765			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Otezla			S	Unknown			Celgene
	Certolizumab Pegol			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Advair	C	Unknown	Not Reported
Allopurinol	C	Unknown	Not Reported
Atrovent Hfa	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
Cyclobenzaprine Hydrochloride	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Esomeprazole Magnesium Hydrate	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Unknown	Not Reported
Ibuprofen	C	Unknown	Not Reported
Leucovorin Calcium	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Ventolin Hfa	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807730	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236781			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Prednisone			S	Oral			Actavis
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram Daily;		Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Humira			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807800	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598497			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apparent Death; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Pulmonary Embolism; Renal Failure	Actemra	S	Unknown	Not Reported
	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S		Not Reported
	Anakinra	S	Unknown	Not Reported
	Anakinra	S		Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S		Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S		Not Reported
	Oxyquinoline Sulfate	S	Unknown	Not Reported
	Oxyquinoline Sulfate	S		Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified) Powder For Solution Intravenous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597720		67 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Dorzolamide			C	Unknown			Not Reported
	Hydrochloride/Timolol Maleate							
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Ophthalmic			Not Reported
	Zingiber Officinale			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807840	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202004826		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tinnitus	Midazolam (Manufacturer Unknown)			S	Unknown	Unk		Fresenius Medical Care
	Ceftriaxon (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Oral	200 Mg/12 H		Not Reported
	Ritonavir/Lopinavir			S	Oral	5 MI/ 12 H (80 Mg + 20 Mg) / MI Oral Solution, 5 Bottles Of 60 MI + 5 Syringes Of 5 MI)		Not Reported

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Azithromycin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Fentanyl	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807858	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200406217		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Levaquin			S	Unknown			Janssen
Abdominal Pain Upper;	Arava			S	Unknown			Not Reported
Arthralgia; Cardiac Failure	Celebrex			S	Unknown			Not Reported
Congestive; Cough;	Cephalexin Monohydrate			S	Unknown			Not Reported
Diarrhoea; Drug	Ciprofloxacin			S	Unknown			Not Reported
Hypersensitivity;	Clindamycin			S	Unknown			Not Reported
Dyspnoea; Gastric	Codeine			S	Unknown			Not Reported
Disorder; Hepatic	Enalapril			S	Unknown			Not Reported
Steatosis; Hypertension;	Enbrel			S	Unknown			Not Reported
Loss Of Employment;	Fosamax			S	Unknown			Not Reported
Nausea; Rash;	Hydralazine Hydrochloride			S	Unknown			Not Reported
Therapeutic Product Effect	Hydrochlorothiazide			S	Unknown			Not Reported
Decreased	Losartan			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Metoprolol Tartrate			S	Unknown			Not Reported
	Moxifloxacin Hydrochloride			S	Unknown			Not Reported
	Pantoprazole Magnesium			S	Unknown			Not Reported
	Pariet			S	Unknown			Not Reported
	Penicillin /00000901/			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Iron Sucrose			C				Not Reported

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Esomeprazole			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807894	EXPEDITED (15-DAY)		OT	ES-ACCORD-182460		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807895	EXPEDITED (15-DAY)		HO	ES-ACCORD-182670		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hyponatraemia	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported	
	Symbicort Turbuhaler			S	Respiratory (inhalation)	2-2-2, 160 Micrograms / 4.5 Micrograms / Inhalation Powder For Inhalation, 1 Inhaler Of 120 Doses		Not Reported	
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported	
	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807925	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2601473		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Apparent Death;	Actemra	S	Unknown	Not Reported
Arthropathy; C-Reactive	Actemra	S		Not Reported
Protein Abnormal;	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Contraindicated Product				
Administered; Deep Vein	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Thrombosis; Diverticulitis;				
Drug Hypersensitivity;	Anakinra	S	Unknown	Not Reported
Drug Ineffective; Drug	Anakinra	S		Not Reported
Intolerance; Feeling	Arava	S	Unknown	Not Reported
Abnormal; Haemoglobin	Arava	S	Unknown	Not Reported
Decreased; Herpes	Enbrel	S	Subcutaneous	Not Reported
Zoster; Intentional Product	Enbrel	S		Not Reported
Use Issue; Interstitial Lung	Humira	S	Subcutaneous	Not Reported
Disease; Joint Swelling;	Humira	S		Not Reported
Myocardial Infarction; Off	Leflunomide	S	Oral	Not Reported
Label Use; Pain;	Leflunomide	S		Not Reported
Photosensitivity Reaction;	Methotrexate	S	Intra-arterial	Not Reported
Pulmonary Embolism;	Methotrexate	S		Not Reported
Pulmonary Thrombosis;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Red Blood Cell	Orencia	S		Not Reported
Sedimentation Rate	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Increased; Renal Failure;	Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Sepsis; Stomatitis;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Terminal State;				
Thrombosis; Urticaria	Remicade	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S		Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported

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Ilaris	S	Subcutaneous	Single-Use Vial	Not Reported
Oxycodone	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Rituximab	C	Unknown		Not Reported
Lyrica	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807933	EXPEDITED (15-DAY)		HO	NVSC2020ES129940		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Product Use In Unapproved Indication	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Bid		Novartis	
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid (For 5-10 Days)		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17807960	EXPEDITED (15-DAY)		OT	DK-PFIZER INC-2020197070		50 YR	Male	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Feet Syndrome; Dry Mouth; Intervertebral Disc Protrusion; Neuropathy Peripheral; Osteopenia; Pain In Extremity; Small Fibre Neuropathy	Methotrexate			S		15 Mg, Weekly		Pfizer	
	Methotrexate			S		20 Mg, Weekly		Pfizer	
	Methotrexate			S		25 Mg, Weekly		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	
	Prednisolone			C	Oral	12.5 Mg, Daily		Not Reported	
	Prednisolone			C	Oral	Dose Reduced		Not Reported	
	Prednisolone			C	Oral	5 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808058	EXPEDITED (15-DAY)		DE, HO	ES-PFIZER INC-2020198873		72 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Meropenem	S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)	Pfizer
	Linezolid	S	Intravenous (not otherwise specified)	600 Mg, 2x/Day (Every 12 Hours)	Pfizer
	Roactemra	S		600 Mg, Single	Not Reported
	Roactemra	S			Not Reported
	Piperacillin/Tazobactam	S	Intravenous (not otherwise specified)	1 Df, 3x/Day (Every 8 Hours)	Not Reported
	Metamizole	S	Intravenous (not otherwise specified)	2 G, 3x/Day (2 G Every 8 Hours)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808093	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598666			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Off Label Use; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Leflunomide			S	Oral			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mirtazapine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808150	EXPEDITED (15-DAY)		OT	NVSC2020ES129943		65 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Interaction; Drug Level Therapeutic;	Lopinavir,Ritonavir	S	Unknown	200/100 Mg, Bid	Not Reported
Gastrointestinal Disorder; Product Use In	Hydroxychloroquine Sulfate	S	Oral	400 Mg, Bid	Novartis
Unapproved Indication; Renal Failure	Hydroxychloroquine Sulfate	S	Oral	200 Mg, Bid (For 5-10 Days)	Novartis
	Tacrolimus	S	Unknown	Unk	Not Reported
	Tacrolimus	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808183	EXPEDITED (15-DAY)		DS	CA-ROCHE-2598082		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; Condition Aggravated;	Alendronate Sodium			S	Oral			Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue;	Arava			S	Oral			Not Reported
Glossodynia; Hand Deformity; Hepatic Enzyme Increased; Hip Arthroplasty; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain;	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Oral			Not Reported
	Topicort [Desoximetasone]			S	Oral			Not Reported
	Topicort [Desoximetasone]			S	Cutaneous			Not Reported
	Topicort [Desoximetasone]			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported

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Folic Acid	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Hydrocortisone Acetate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Oral	11.0 Years	Not Reported
Methotrexate Sodium	S	Oral		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Subcutaneous		Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Subcutaneous		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	365.0	Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	365.0	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported

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20-May-2020	17808262	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600334			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Off Label Use; Oral Discomfort; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808273	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597830		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill-	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

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Defined Disorder; Lung Disorder; Lupus-Like Syndrome;	Arava	S	otherwise specified)	Not Reported
Musculoskeletal Stiffness; Off Label Use; Pain;	Celebrex	S	Unknown	Not Reported
Quality Of Life Decreased; Rheumatoid Arthritis;	Enbrel	S	Oral	Not Reported
Therapy Non-Responder; Tuberculin Test Positive	Humira	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Toradol	S	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808302	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598106			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown	Therapy Duration: 577		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 577		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 577		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 5 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 577		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Hydroxychloroquine	S	Oral	Therapy Duration: 577	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Methotrexate	S	Unknown	Therapy Duration: 577	Not Reported
Methotrexate	S	Unknown	Therapy Duration: 577	Not Reported
Methotrexate	S	Unknown	Therapy Duration: 577	Not Reported
Orencia	S	Unknown	Therapy Duration: 577	Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Therapy Duration: 577	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 577	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Simponi	S	Subcutaneous	Therapy Duration: 577	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599535		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808362	EXPEDITED (15-DAY)		OT	NVSC2020IL137300		43 YR	Male	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder; Product Use In Unapproved Indication; Retinal Injury	Methotrexate			S	Unknown	20 Mg, Qw		Novartis
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Azathioprine			C	Unknown	3 Mg/Kg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808452	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599352			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Drug Ineffective;	Actemra			S	Intravenous (not			Not Reported

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Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab	S	otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808581	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236786			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During	Methotrexate			S	Unknown			Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

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Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosis; Wound	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S			Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquine Phosphate]]	S		400 Milligram Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808608	EXPEDITED (15-DAY)		DE	ES-PFIZER INC- 2020198882		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, 1x/Day		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Mg, 1x/Day		Not Reported	

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Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, Single	Not Reported
Tocilizumab	S			Not Reported
Dexketoprofen	S	Intravenous (not otherwise specified)	25 Mg, 3x/Day (Every 8 Hours)	Not Reported
Hydroxychloroquine	S	Oral	400 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808609	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198940		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Supraventricular Tachycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808668	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000390			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hepatocellular Injury; Off Label Use	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus	
	Plaquenil /00072603/			S	Oral	Unk		Not Reported	
	Plaquenil /00072603/			S				Not Reported	
	Rovamycin /00074401/			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Paracetamol			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Linezolid Kabi			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Movicolon			C		Unk		Not Reported	
	Amikacin /00391002/			C		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808728	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR- 2020VAL000391			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Off Label Use; Purpura; Thrombocytopenia	Cefotaxime Sodium			S	Intravenous (not otherwise specified)	Unk		Validus	
	Plaquenil /00072603/			S	Oral	Unk		Not Reported	
	Plaquenil /00072603/			S				Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Esomeprazole Magnesium			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Lovenox			S	Subcutaneous	Unk		Not Reported	
	Noradrenaline /00127501/			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Loxen /00639802/			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Nimbex /01302502/			C		Unk		Not Reported	
	Sufentanil			C		Unk		Not Reported	
	Hypnovel /00634103/			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808802	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236733			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Prednisone			S	Unknown			Actavis	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cimzia	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17808803	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1236789		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Drug Ineffective; Hypersensitivity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosis; Treatment Failure	Methotrexate			S	Unknown	20 Milligram Daily;		Barr
	Methotrexate			S				Barr
	Prednisone			S	Unknown			Actavis
	Alendronate Sodium			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

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Folic Acid	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17809219	EXPEDITED (15-DAY)		OT	CA-SA-2018SA288283		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol	Arava			S	Unknown			Sanofi

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Drug	Methotrexate	S	Unknown		Not Reported
Hypersensitivity; Drug	Plaquenil Sulfate	S	Unknown		Sanofi
Ineffective;	Enbrel	S	Unknown		Not Reported
Hypersensitivity; Insomnia;	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Loss Of Personal Independence In Daily Activities; Pain;	Remicade	C	Unknown		Not Reported
Rheumatoid Arthritis; Stress At Work; Swelling	Acetaminophen And Codeine Phosphate	C	Unknown		Not Reported
	Cimzia	C			Not Reported
	Humira	C	Unknown		Not Reported
	Orencia	C	Unknown		Not Reported
	Actemra	C	Unknown		Not Reported
	Simponi	C	Unknown		Not Reported
	Lyrica	C	Unknown	Unk	Not Reported
	Arthrotec	C	Unknown		Not Reported
	Tylenol [Paracetamol]	C	Unknown	Unk	Not Reported
	Rabeprazole	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17809246	EXPEDITED (15-DAY)		OT	CA-SA-2019SA058842		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Injury; Joint Swelling;	Hydroxychloroquine			S				Sanofi
Pain; Peripheral Swelling;	Methotrexate			S				Not Reported
Retinal Injury; Swelling	Leflunomide			S				Sanofi
	Actemra			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810378	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3409473-00			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Ageusia; Anosmia; Blindness; Blood Lactate Dehydrogenase Abnormal; Diarrhoea; Fatigue; Gamma- Glutamyltransferase Abnormal; Hypoacusis; Malaise; Nervousness; Off Label Use	Kaletra	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17810521	EXPEDITED (15-DAY)		OT	CA-ROCHE-1857550			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17811001	DIRECT	Y	HO			53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	11457282	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1626689			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Discomfort; Arthralgia; Coeliac Disease; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nail Disorder; Nail Operation; Onychomadesis; Onychomycosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Xeljanz			S	Unknown			Not Reported	
Xeljanz			S	Unknown			Not Reported	
Apo-Hydroxyquine			S	Unknown			Not Reported	

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Hydroxychloroquine	S	Unknown	Not Reported
Infliximab	S	Unknown	Not Reported
Infliximab	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	11631404	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1643958			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Asthenia; Condition Aggravated;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Cough;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Drug Ineffective; Drug Ineffective; Drug	Naprosyn [Naproxen]			S	Unknown			Not Reported
Ineffective; Fatigue; Fine	Orencia			S	Unknown			Not Reported
Motor Skill Dysfunction; Goitre; Headache;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Inflammation; Joint Swelling; Lower	Methotrexate Sodium			S	Oral			Not Reported
Respiratory Tract Infection; Musculoskeletal	Enbrel			S	Subcutaneous			Not Reported
Pain; Musculoskeletal Stiffness; Nasopharyngitis;	Prednisone			S	Oral			Not Reported
Nephrolithiasis; Pain; Pain	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported

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In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Sulfasalazine	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Ketoprofen	C	Unknown	Not Reported
	Losec [Omeprazole]	C		Not Reported
	Citalopram Hydrobromide	C		Not Reported
	Crestor	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Rosuvastatin Calcium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	12130379	EXPEDITED (15-DAY)		OT	CA-ROCHE-1717281			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Intentional Product Use Issue; Lymphoma; Neoplasm Malignant; Off	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

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Label Use; Onychoclasia; Onychoclasia; Synovitis; Tooth Loss	Orencia	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Zostavax	S	Subcutaneous	Not Reported
	Zostavax	S	Unknown	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Cortisone	C	Oral	Not Reported
	Voltaren [Diclofenac]	C	Unknown	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Desoximetasone	C	Unknown	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	12909635	EXPEDITED (15-DAY)		OT	CA-ROCHE-1564010		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Ineffective; Drug Intolerance; Erythema; Fatigue; Hepatic Enzyme Increased; Pain; Skin Reaction; Skin Swelling; Swelling	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	12974904	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-1859498		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Impaired Work Ability; Joint Swelling; Red Blood Cell Sedimentation Rate Increased; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not			Not Reported

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		otherwise specified)	
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Bupropion	C		Not Reported
Esomeprazole	C		Not Reported
Folic Acid	C		Not Reported
Levothyroxine	C		Not Reported
Naproxen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	13091577	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875078		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	13100775	EXPEDITED (15-DAY)		OT	CA-ROCHE-1877150			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal;	Actemra			S	Unknown			Not Reported
Condition Aggravated;	Actemra			S	Unknown			Not Reported
Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Diarrhoea;	Actemra			S	Unknown			Not Reported
Disease Progression;	Actemra			S	Unknown			Not Reported
Drug Hypersensitivity;	Rituxan			S	Unknown			Not Reported
Drug Ineffective; Drug	Mycophenolate Mofetil			S	Unknown			Not Reported
Intolerance;	Actemra			S	Intravenous (not			Not Reported
Hypersensitivity;					otherwise specified)			
Laryngeal Disorder;	Actemra			S	Intravenous (not			Not Reported
Nausea; Off Label Use;					otherwise specified)			
Product Use Issue;	Rituximab			S	Intravenous (not			Not Reported
Pruritus; Psoriatic					otherwise specified)			
Arthropathy; Rash;	Enbrel			S	Unknown			Not Reported
Rheumatoid Arthritis;	Enbrel			S	Unknown	08/--/2002 To 05/--/2005		Not Reported
Sciatica; Sinusitis;	Enbrel			S	Unknown	Duration 730 Days		Not Reported
Sinusitis; Stomatitis;	Arava			S	Oral	Dose And Frequency		Not Reported
Therapeutic Product Effect						Unknown.		
Incomplete; Therapeutic	Arava			S	Oral			Not Reported
Product Effect Incomplete;	Arava			S	Unknown			Not Reported
Treatment Failure;	Cimzia			S	Subcutaneous			Not Reported
Treatment Failure; Weight	Cimzia			S	Subcutaneous			Not Reported
Decreased	Cimzia			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Imuran [Azathioprine]	S	Unknown	Dose And Frequency Unknown	Not Reported
Sulfasalazine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Sulfasalazine	S	Unknown		Not Reported
Ciclosporin	S	Oral	Dose And Frequency Unknown.	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Dose And Frequency Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Certolizumab	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown	Dose And Frequency Unknown.	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cyclosporine	S	Oral	Dose And Frequency Unknown	Not Reported
Cyclosporine	S	Unknown		Not Reported
Cyclosporine	S	Oral		Not Reported
Cyclosporine	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown	Dose And Frequency Unknown.	Not Reported
Azathioprine	S	Unknown	Dose And Frequency Unknown.	Not Reported
Lyrica	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Gold	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Prednisone	C			Not Reported
Piroxicam	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	13166185	EXPEDITED (15-DAY)		OT	CA-ROCHE-1886967		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	13213527	EXPEDITED (15-DAY)		OT	CA-SA-2015SA178531		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
	Leflunomide			S	Unknown	20 Mg,Qd		Sanofi
	Methotrexate			S	Oral	10 Mg,Qw		Not Reported
	Methotrexate			S	Oral	20 Mg,Qw		Not Reported
	Methotrexate			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg,Unk		Not Reported
	Enbrel			S	Unknown	Unk Unk,Unk		Not Reported
	Enbrel			S	Unknown	1 Df,Unk		Not Reported
	Mefenamic Acid			S	Unknown	400 Mg,Bid		Not Reported
	Xeljanz			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Unknown	Unk Unk,Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg,Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	14287715	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2035078		74 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sciatica; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Altace			S	Unknown	1 Unit Not Reported		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Cosopt			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	14831436	EXPEDITED (15-DAY)		OT	CA-ROCHE-2112282		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Hypersensitivity; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
Arava	S	Unknown		Not Reported
Enbrel	S	Subcutaneous	Therapy Duration: 8 Years	Not Reported
Enbrel	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Orencia	S	Subcutaneous		Not Reported
Rituximab	S	Intravenous drip		Not Reported
Simponi	S	Subcutaneous		Not Reported
Meloxicam	C	Oral		Not Reported
Prednisolone	C			Not Reported
Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	15327981	EXPEDITED (15-DAY)		OT	CA-ROCHE-2175377		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Disease Recurrence; Drug Ineffective; Joint Swelling; Lower Respiratory Tract Infection; Pulmonary	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Arthrotec	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	15674323	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2018US050584			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphopenia; Premature Baby	Tacrolimus			S	Transplacental	Unk, Unknown Freq.		Astellas
	Hydroxychloroquine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Azathioprine			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Transplacental	Unk Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	15843598	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190118854		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Diarrhoea; Drug Ineffective; Infection; Joint Swelling; Lower Respiratory Tract Infection; Palpitations; Pulmonary Mass; Rheumatoid Arthritis; Rheumatoid Factor Positive	Remicade	S	Intravenous (not otherwise specified)	Janssen
	Simponi	S	Subcutaneous	Janssen
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown	Not Reported
	Arava	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arthrotec	C	Oral	Not Reported
	Gold	C	Unknown	Not Reported
	Imuran	C	Unknown	Not Reported
	Vitamin D	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	15929079	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832232		55 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	16318010	EXPEDITED (15-DAY)		HO	EC-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-207974		14 YR	Female	ECU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Posterior Reversible Encephalopathy Syndrome	Atorvastatin			S	Unknown	10 Milligram		Sun
	Atorvastatin			S				Sun
	Enalapril			S	Unknown	5 Milligram		Ranbaxy
	Enalapril			S				Ranbaxy
	Furosemide			S	Unknown	40 Milligram		Sun
	Furosemide			S				Sun
	Hydroxychloroquine			S	Unknown	200 Milligram		Ipca
	Hydroxychloroquine			S				Ipca
	Prednisone			S	Unknown	30 Milligram		Mutual
	Prednisone			S				Mutual

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	16646741	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202691			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Drug	Hydroxychloroquine Sulfate	S		200 Mg, Biw	Sanofi
Ineffective; Hepatitis;	Hydroxychloroquine Sulfate	S		400 Mg, Tiw	Sanofi
Inflammation; Joint	Leflunomide	S			Sanofi
Swelling; Musculoskeletal	Leflunomide	S			Sanofi
Stiffness; Off Label Use;	Methotrexate	S	Subcutaneous	20 Mg, Qw	Not Reported
Rheumatoid Arthritis;	Sulfasalazine	S			Not Reported
Therapeutic Product Effect	Actemra	S	Subcutaneous	162 Mg, Qow	Not Reported
Decreased; Treatment	Adalimumab	S	Subcutaneous	40 Mg, Qow	Not Reported
Failure	Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
	Orencia	S		Unk	Not Reported
	Prednisone	C		20 Mg, Qd	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	16770849	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1100415			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia;	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1		Actavis
Arthropathy; Ligament						Number Of Units In The		
Sprain; Nasopharyngitis;						Interval: 12 Definition Of		
Oedema Peripheral; Pain						The Interval: Hour		
In Extremity;	Omeprazole			S	Oral	40 Milligram Daily; 20 Mg,		Actavis
Paraesthesia; Peripheral						Bid		
Coldness; Pulmonary	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1		Actavis
Hypertension; Therapeutic						Number Of Units In The		
Product Effect Incomplete;						Interval: 12 Definition Of		
Visual Impairment						The Interval: Hour		
	Ramipril			S		5 Milligram Daily;		Actavis
	Sildenafil Citrate			S	Unknown	60 Milligram Daily;		Actavis
	Volibris			S	Oral	30 Milligram Daily;		Not Reported
	Volibris			S	Oral	1 Dosage Forms Daily;		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qwk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd; 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd; Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Spasmolyt	S	Unknown	15 Milligram Daily;	Not Reported
Spasmolyt	S	Unknown	30 Milligram Daily;	Not Reported
Quensyl	S	Unknown	80 Milligram Daily; 40 Mg, Bid	Not Reported
Quensyl	S	Unknown	40 Milligram Daily; 20 Mg, Bid	Not Reported
Ambrisentan	S	Oral	1 Dosage Forms Daily;	Not Reported
Ambrisentan	S	Unknown	30 Milligram Daily;	Not Reported
Lyrica	S	Unknown	100 Milligram, Tid	Not Reported
Lyrica	S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1)	Not Reported
Apixaban	S	Unknown	10 Milligram Daily; 2.5 Milligram, Bid	Not Reported
Apixaban	S	Unknown	2 Dosage Forms Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	16906561	EXPEDITED (15-DAY)	HO		CA-ROCHE-2425931		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Contraindicated Product Administered; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug	Rituxan			S	Intravenous drip			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Drug	Leflunomide	S	Unknown	Not Reported
Tolerance Decreased; Hip	Methotrexate	S	Unknown	Not Reported
Arthroplasty; Infection;	Orencia	S	Unknown	Not Reported
Knee Arthroplasty; Off	Simponi	S	Subcutaneous	Not Reported
Label Use; Seronegative	Sulfasalazine	S	Unknown	Not Reported
Arthritis; Spinal Fusion	Apo-Leflunomide	S	Unknown	Not Reported
Surgery; Therapeutic	Hydroxychloroquine	S	Unknown	Not Reported
Product Effect Decreased;	Naprosyn [Naproxen]	C	Unknown	Not Reported
Type 2 Diabetes Mellitus;	Erythromycin	C		Not Reported
Wound Infection	Morphine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17012579	EXPEDITED (15-DAY)		DS	CA-ROCHE-2458308			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy;	Actemra			S	Unknown			Not Reported
Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Drug	Rituxan			S	Unknown			Not Reported
Ineffective; Liver Function	Cimzia			S	Subcutaneous			Not Reported
Test Increased;	Enbrel			S	Unknown			Not Reported
Therapeutic Product Effect	Humira			S	Subcutaneous			Not Reported
Decreased	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Tocilizumab	S	Unknown	Not Reported
	Imuran [Azathioprine]	C	Unknown	Not Reported
	Azathioprine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17250075	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516466			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Tocilizumab			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17371160	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2538246		60 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Off Label Use; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Diclofenac Potassium			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17386806	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-20200111049		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Parathyroid Hormone Decreased; C- Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In	Otezla			S	Oral	120 Milligram		Celgene
	Otezla			S				Celgene
	Otezla			S				Celgene
	Alendronate Sodium			S	Unknown	70 Milligram		Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	7.1429 Milligram		Not Reported
	Enbrel			S	Subcutaneous	7.1429 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Daily Activities; Nausea;	Enbrel	S			Not Reported
Panniculitis; Peripheral	Humira	S	Subcutaneous	40 Milligram	Not Reported
Swelling; Psoriatic	Humira	S			Not Reported
Arthropathy; Rash; Rash	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Pruritic; Red Blood Cell		S			Not Reported
Sedimentation Rate;	Ibuprofen	S	Oral	600 Milligram	Not Reported
Rheumatoid Arthritis;	Ibuprofen	S	Oral		Not Reported
Rheumatoid Nodule; Skin	Infliximab	S	Oral		Not Reported
Necrosis; Skin Ulcer;	Leflunomide	S	Oral		Not Reported
Synovitis; Tendonitis;	Leflunomide	S	Oral		Not Reported
Tenosynovitis; Tongue	Leflunomide	S	Oral		Not Reported
Disorder; Ulcer	Methotrexate	S	Unknown	12.5 Milligram	Not Reported
	Methotrexate	S	Unknown	.1096 Milligram	Not Reported
	Methotrexate	S	Unknown	.1315 Milligram	Not Reported
	Methotrexate	S	Unknown	17.5 Milligram	Not Reported
	Methotrexate	S	Unknown	15 Milligram	Not Reported
	Methotrexate	S	Unknown	70 Milligram	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	360 Milligram	Not Reported
	Tocilizumab	S	Unknown	680 Milligram	Not Reported
	Sulfasalazine	S	Endocervical		Not Reported
	Stelara	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous drip	2000 Milligram	Not Reported
	Remicade	S	Intravenous drip		Not Reported
	Benadryl	S	Unknown		Not Reported
	Mogadon	C	Oral	5 Milligram	Not Reported
	Colchicine	C	Unknown		Not Reported
	Nitrazepam	C	Oral	5 Milligram	Not Reported
	Dexilant	C	Oral		Not Reported
	Febuxostat	C	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Uloric	C	Oral	160 Milligram
Oxycodone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17395477	EXPEDITED (15-DAY)		OT	CA-ROCHE-2542443		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported
Arthropathy; Bone	Rituxan			S	Intravenous (not			Not Reported
Disorder; Condition					otherwise specified)			
Aggravated;	Arava			S	Unknown			Not Reported
Contraindicated Product	Enbrel			S	Subcutaneous			Not Reported
Administered; Drug	Humira			S	Subcutaneous			Not Reported
Hypersensitivity; Drug	Hydroxychloroquine			S	Unknown			Not Reported
Ineffective; Finger	Methotrexate			S	Unknown			Not Reported
Deformity; Off Label Use;	Orencia			S	Intravenous (not			Not Reported
Pain; Peripheral Swelling;					otherwise specified)			
Rash; Swelling; Tendon	Remicade			S	Intravenous (not			Not Reported
Disorder; Tenosynovitis;					otherwise specified)			
Treatment Failure;	Gold			S	Unknown			Not Reported
Urticaria	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Penicillin G Sodium			S	Unknown			Not Reported
	Penicillin V Potassium			S	Unknown			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sodium Aurothiomalate	S	Parenteral	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17460784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2554332			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Depression; Drug Ineffective; Feeling Abnormal; Foot Deformity; Hand Deformity; Leukopenia; Limb Deformity; Musculoskeletal Pain; Pain; Pain In Extremity; Pruritus; Rash; Squamous Cell Carcinoma; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported
	Neoral			S	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Citalopram Hydrobromide			C	Unknown	1.0 Dosage Forms		Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17570483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570439		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17579775	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200327856		38 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Arthropathy; Diabetes Mellitus; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Erythema; Impaired Work Ability; Knee Arthroplasty; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Musculoskeletal Disorder; Skin Warm; Spinal Stenosis; Therapeutic Product Effect Decreased; Urinary Tract Infection	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Gold			C				Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prednisone			C	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17605656	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200332784		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; No Adverse Event; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Endocervical	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	C	Oral	Not Reported
And Xeljanz Xr (Prolonged Release)			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17702479	EXPEDITED (15-DAY)		OT	AU-ABBVIE-20K-008-3373197-00			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	



Detailed Report

Abdominal Pain Upper; Ageusia; Arthralgia;	Humira	S	Subcutaneous	Not Reported
Depression; Dna Antibody Negative; Drug Interaction;	Oxycontin	S	Unknown	Not Reported
Fibromyalgia; Gait Disturbance; Liver	Sildenafil	S	Oral	Not Reported
Function Test Abnormal;	Glyceryl Trinitrate	S	Oral	Not Reported
Migraine; Nausea; Panic Attack; Paraesthesia;	Prasugrel	S	Unknown	Not Reported
Psoriasis; Psoriatic Arthropathy; Respiratory	Novorapid	S	Subcutaneous	Not Reported
Syncytial Virus Infection;	Topiramate	S	Unknown	Not Reported
Sleep Disorder; Suicidal Ideation; Systemic Lupus	Glucagen	S	Unknown	Not Reported
Erythematosus;	Methotrexate	S	Subcutaneous	Not Reported
Tachyarrhythmia; Type 1 Diabetes Mellitus; Urinary	Methotrexate	S	Subcutaneous	Not Reported
Tract Infection; Viral Tonsillitis	Methotrexate	S	Subcutaneous	Not Reported
	Reboxetine	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Rosuvastatin Calcium	S	Unknown	Not Reported
	Ezetimibe	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Ramipril	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Endone	S	Unknown	Not Reported
	Ivabradine	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Oral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisolone	S	Unknown	Not Reported
	Cholecalciferol	S	Unknown	Not Reported
	5-Methyltetrahydrofolate	S	Unknown	Not Reported
	Cannabis Sativa Oil	S	Unknown	Not Reported
	Mirena	S	Unknown	Not Reported

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17703460	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020222		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Nivaquine			S	Oral	200 Milligram, Once A Day (2-3 Cp Per Day)		Not Reported	
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17742017	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020078		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Intentional Product Use Issue; Pyrexia	Amoxicillin			S	Oral	3 Gram, Once A Day		Aurobindo	
	Hydroxychloroquine Sulfate			S	Oral	800 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17743899	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589699		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Hypersensitivity; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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Apo-Leflunomide	S	Unknown	Not Reported
Rituxan	S	Intravenous drip	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Meloxicam	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17747147	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200436816			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Hand Deformity; Hip Arthroplasty; Impaired Work Ability; Joint Swelling; Knee Arthroplasty; Polyarthritis; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			S	Oral			Not Reported
	Indometacin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17767661	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2020180079			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Death; Off Label Use;	Azithromycin	S	Unk	Pfizer
Product Use In	Plaquenil [Hydroxychloroquine Sulfate]	S	Unk	Not Reported
Unapproved Indication				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17771128	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1045669		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported	
	Nivaquine /00001003/			S	Oral	200 Milligram, Qd (2-3 Cp Par Jour)		Mylan	
	Plaquenil /00072602/			S	Oral	2-3 Cp Par Jour		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17772547	EXPEDITED (15-DAY)		OT	ES-FRESENIUS KABI-FK202004490		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Long Qt Syndrome	Midazolam (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Midazolam (Manufacturer Unknown)			S				Fresenius Medical Care	
	Propofol (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Propofol (Manufacturer Unknown)			S				Fresenius Medical Care	
	Ceftriaxon (Manufacturer Unknown)			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Ritonavir/Lopinavir			S	Oral			Not Reported	
	Zea Mays Extract			C	Unknown			Not Reported	
	Formoterol			C	Unknown			Not Reported	
	Fumarate/Budesonide								
	Tamsulosin Hydrochloride			C	Unknown			Not Reported	
	Simvastatin			C	Unknown			Not Reported	

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Detailed Report

Valsartan	C	Unknown	Not Reported
Hydrocortisone Acetate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17773513	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-246919		96 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Extrasystoles; Off Label Use	Azithromycin			S	Unknown	500 Milligrams, Daily, Tablet		Sun
	Plaquenil			S	Unknown	400 Milligrams, Daily		Not Reported
	Lasix 25 Mg Compresse			C	Unknown	25 Milligrams, Daily		Not Reported
	Novorapid			C	Unknown	Unk		Not Reported
	Normix			C	Unknown	Unk		Not Reported
	Dobetin			C	Unknown	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Movicol			C	Unknown	Unk		Not Reported
	Deltacortene 25 Mg Compresse			C	Unknown	Unk		Not Reported
	Pantorc 20 Mg Compresse			C	Unknown	20 Milligrams, Daily		Not Reported
	Gastroresistenti Cardirene 75 Mg			C	Unknown	75 Milligrams, Daily		Not Reported
	Metoprololo			C	Unknown	50 Milligrams, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17787974	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC- 2020191657			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label	Azithromycin			S		Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported

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Use; Product Use In
Unapproved Indication;
Ventricular Arrhythmia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17801314	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247202		78 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Long Qt Syndrome	Midazolam			S	Unknown	Unk		Sun
	Midazolam			S				Sun
	Azithromycin			S	Unknown	Unk		Sun
	Propofol			S	Unknown	Unk		Not Reported
	Propofol			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos			S	Oral	200 Milligram, Bid		Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Ceftriaxona (501a)			S	Unknown	Unk		Not Reported
	Omnice Ocas 0,4 Mg Comprimidos De Liberacion Prolongada Recubiertos ...			C	Unknown	Unk		Not Reported
	Cortic - Corticoide			C	Unknown	Unk		Not Reported
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprim...			C	Unknown	Unk		Not Reported
	Rilast Turbuhaler 160 Microgramos/4,5			C	Unknown	Unk		Not Reported
	Microgramos/Inhalacion Polvo...							
	Simvastatina 20 Mg 28 Comprimidos			C	Unknown	Unk		Not Reported
	Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimido...			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17804027	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES- 1235537		43 YR	Male	ESP

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Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Aggression; Behaviour Disorder	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809266	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-025598		58 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Atrial Fibrillation; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram, Once A Day		Not Reported	
	Enoxaparin			S	Subcutaneous	80 Milligram, Two Times A Day		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809432	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247759		49 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Mg Dia		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17809442	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-025271		61 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Electrocardiogram Qt Prolonged	Amoxicillin			S	Oral	3 Gram		Aurobindo	
	Clavulanic Acid			S	Oral	600 Milligram		Not Reported	

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Plaquenil			S	Oral	600 Milligram			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809472	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2020-019736		75 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809535	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599814		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Decreased; Colitis; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Headache; Joint Swelling; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Tremor; Vitamin D Deficiency	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Amlodipine Besilate			S	Oral			Not Reported	
	Asacol			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	

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	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Bisoprolol Fumarate	C		Not Reported
	Depo-Medrol	C	Intra-articular	Not Reported
	Ferrous Gluconate	C		Not Reported
	Folic Acid	C		Not Reported
	Pantoprazole Magnesium	C		Not Reported
	Tenofovir Disoproxil Fumarate	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin D3	C		Not Reported
	Xeljanz	C		Not Reported
	Zopiclone	C		Not Reported
	Atacand Plus	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809571	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599460		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Chronic Kidney Disease; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Stiffness; Musculoskeletal Stiffness; Sepsis; Synovitis; Systemic Lupus Erythematosus; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Amoxicillin Sodium;Clavulanate Potassium			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin;Clavulanate Potassium			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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				otherwise specified)					
		Sulfasalazine		S	Unknown				Not Reported
		Plaquenil [Hydroxychloroquine Sulfate]		C	Unknown				Not Reported
		Prednisone		C	Unknown				Not Reported
		Tridural		C	Unknown				Not Reported
		Tylenol		C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809623	EXPEDITED (15-DAY)		OT	HR-ADVANSZ PHARMA-GSH201801-000311			Unknown	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscular Weakness; Phospholipidosis; Proteinuria; Renal Disorder; Renal Impairment; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	500 Mg, Qd, Tablet		Concordia	
	Azathioprine			C		50 Mg, Bid		Not Reported	
	Prednisolone			C		10 Mg, Qd		Not Reported	
	Levothyroxine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809624	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599977			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Aspirin [Acetylsalicylic Acid]	C		Not Reported
Synthroid	C		Not Reported
Cymbalta	C		Not Reported
Hydromorphone	C		Not Reported
Remicade	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599612		49 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pain; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809723	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601836		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Angioedema; Drug Ineffective; Drug Intolerance; Dyspepsia; Food Intolerance; Hepatic Enzyme Increased; Hypertension; Injection Site Inflammation; Off Label Use; Pneumonia; Pruritus; Rheumatoid Arthritis; Urosepsis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methyl Salicylate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809833	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-247680		66 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Purpura; Thrombocytopenia	Azithromycin			S	Oral	Unk		Sun
	Noradrenaline			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cefotaxime Base			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Inexium			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Lovenox			S	Subcutaneous	Unk		Not Reported
	Loxen (Nicardipine Chlorhydrate)			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil	S	Oral	Unk	Not Reported
Hypnovel	C	Unknown	Unk	Not Reported
Sufentanil	C	Unknown	Unk	Not Reported
Nimbex	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599524			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809981	EXPEDITED (15-DAY)		OT	ES-ACCORD-182511		45 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Enoxaparin			S	Subcutaneous	40 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17809997	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601414			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Drug Ineffective; Hypersensitivity; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Unknown			Not Reported	
	Rituxan			S				Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S				Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Simponi			C	Subcutaneous			Not Reported	
	Xeljanz			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810098	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599567		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Deformity; Drug Ineffective; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Pain; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Adalimumab			S	Unknown	Therapy Duration: 9.0 Years		Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 05 Years		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 09 Years		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 15 Years		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
Prednisone			C	Unknown			Not Reported	
Prednisone			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810101	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598069			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810102	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599579		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption; Drug Ineffective; Fatigue; Loose Body In Joint; Off Label Use; Osteoporotic Fracture; Pain; Synovitis	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown	2.0 Dosage Form		Not Reported	
	Naproxen			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810198	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598368			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Naproxen			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Triamcinolone Acetonide			S	Intra-articular			Not Reported
	Immunoglobulins [Immunoglobulins Nos]			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810199	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA- 202005005434			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged	Hydroxychloroquine	S	Unk	Concordia					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810200	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005435			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Electrocardiogram Qt Prolonged; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810305	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-247893		71 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg ; In Total		Not Reported	
	Hidroxyclozoquina (2143a)			S	Oral	400 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810415	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598506		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810508	EXPEDITED (15-DAY)		OT	CA-ROCHE-1962205			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Gold Sodium Thiomalate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810519	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-024941		48 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Tachycardia	Amlodipine+Valsartan Film-Coated Tablet	S	Oral	Unk	Aurobindo
	Hydroxychloroquine Sulfate	S	Oral	400 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810579	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598008		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S				Not Reported
	Desoximetasone			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810580	EXPEDITED (15-DAY)		DE, HO, LT	CA-ROCHE-2601602		58 YR	Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C-Reactive Protein	Rituximab			S	Unknown			Not Reported
Abnormal; C-Reactive Protein Increased;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Deep Vein Thrombosis; Diverticulitis;	Actemra			S				Not Reported
Drug Hypersensitivity;	Anakinra			S	Unknown			Not Reported
Drug Ineffective; Drug Intolerance; Feeling	Anakinra			S				Not Reported
Abnormal; Haemoglobin Decreased; Herpes	Apo-Leflunomide			S	Unknown			Not Reported
Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Apo-Leflunomide			S				Not Reported
Joint Swelling; Myocardial Infarction; Off Label Use;	Arava			S	Unknown			Not Reported
Pain; Photosensitivity Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Cannabis Sativa			S	Unknown			Not Reported
Increased; Renal Failure; Sepsis; Stomatitis; Terminal State;	Enbrel			S	Subcutaneous			Not Reported
Thrombosis; Urticaria	Enbrel			S				Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Ilaris			S	Subcutaneous			Not Reported
	Ilaris			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

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Plaquenil [Hydroxychloroquine Sulfate]	S		Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sodium Aurothiomalate	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S		Not Reported
Xeljanz	S	Oral	Not Reported
Rituximab	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810597	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599648			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Off Label Use; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Leflunomide			S	Oral	6.0 Years		Not Reported
	Leflunomide			S	Intramuscular			Not Reported
	Leflunomide			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown	Not Specified		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	4.0 Years		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Oral	6.0 Years	Not Reported
Methotrexate	S	Intramuscular		Not Reported
Methotrexate	S	Oral	6.0 Years	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Prednisone	C	Unknown		Not Reported
Ramipril	C	Unknown	Not Specified	Not Reported
Vitamin D3	C	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Calcium	C	Unknown		Not Reported
Ergocalciferol	C	Unknown		Not Reported
Insulin	C	Unknown		Not Reported
Lantus	C	Subcutaneous		Not Reported
Lozide [Indapamide]	C	Unknown		Not Reported
Metformin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810677	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600210		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Inappropriate Schedule Of Product Administration; Liver Function Test Increased; Rash; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Prednisone	C		Not Reported
Simponi	C	Subcutaneous	Not Reported
Sulfasalazine	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810690	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602929			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Synthroid	C		Not Reported
Xeljanz	C		Not Reported
Meloxicam	C	Unknown	Not Reported
Acetaminophen And Codeine Phosphate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810709	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598248			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Hepatic Enzyme Increased; Hypertension; Off Label Use; Pneumonia; Skin Reaction; Synovitis; Thyroid Disorder; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]			C	Unknown			Not Reported
	Baclofen			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Calcium	C	Unknown	Not Reported
Calcium Gluconate	C	Unknown	Not Reported
Dorzolamide	C	Unknown	Not Reported
Hydrochloride/Timolol Maleate			
Ergocalciferol	C	Unknown	Not Reported
Estradiol	C	Unknown	Not Reported
Estrogel	C	Unknown	Not Reported
Furosemide	C	Unknown	Not Reported
Gravol	C		Not Reported
Levaquin	C	Unknown	Not Reported
Morphine	C		Not Reported
Potassium Chloride	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Xalatan	C	Ophthalmic	Not Reported
Zingiber Officinale	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810788	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599751			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Off Label Use; Pain In Extremity; Rheumatoid Arthritis; Synovitis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Apo-Lefflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methylprednisolone	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Unknown Rectal Gel	Not Reported
Xeljanz	S	Unknown	Not Reported
Naproxen	C		Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810800	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599770		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Adverse Drug Reaction;	Adalimumab			S	Subcutaneous			Not Reported
Anti-Cyclic Citrullinated	Arava			S	Unknown			Not Reported
Peptide Antibody Positive;	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
C-Reactive Protein	Enbrel			S	Subcutaneous			Not Reported
Increased; Drug	Gold			S	Unknown			Not Reported
Ineffective; Intentional	Humira			S	Subcutaneous			Not Reported
Product Use Issue; Joint	Leflunomide			S	Oral			Not Reported
Swelling; Leukopenia;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Musculoskeletal Stiffness;	Orencia			S	Subcutaneous			Not Reported
Off Label Use; Pain; Rash;	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
Rheumatoid Arthritis;	Sodium Aurothiomalate			S	Unknown			Not Reported
Rheumatoid Factor	Acetaminophen			C	Unknown			Not Reported
Positive; Swelling;								
Therapeutic Product Effect								
Decreased; Therapeutic								
Product Effect Incomplete;								
Toxicity To Various								
Agents; Visual Impairment								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methotrexate	C	Subcutaneous	Not Reported
Methylprednisolone Acetate	C		Not Reported
Prednisone	C		Not Reported
Sulfasalazine	C	Oral	Not Reported
Tylenol	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810817	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599854		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Kevzara	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810820	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599662			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Intravenous (not			Not Reported
Alopecia; Fatigue;					otherwise specified)			
Glossodynia; Off Label	Apo-Prednisone			S	Unknown			Not Reported
Use; Pain; Pemphigus;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling; Systemic Lupus Erythematosus	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Desoximetasone	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydrocortisone Acetate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810842	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600284		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600648			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Headache; Hypersensitivity Vasculitis;	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypertension;	Orencia	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported
Nausea; Off Label Use;	Sulfate]			
Rash; Respiratory Tract	Sulfasalazine	S	Unknown	Not Reported
Infection; Rheumatoid				
Arthritis; Therapeutic	Xeljanz	S	Oral	Not Reported
Product Effect Decreased				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810898	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600537		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein	Rituximab			S	Intravenous drip			Not Reported
Increased;	Rituximab			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Interstitial Lung	Leflunomide			S	Unknown			Not Reported
Disease; Joint Swelling;								
Lung Disorder;	Methotrexate			S	Unknown	7.0 Years		Not Reported
Musculoskeletal Stiffness;	Orencia			S	Unknown			Not Reported
Pain; Palpitations; Red								
Blood Cell Sedimentation	Plaquenil [Hydroxychloroquine			S	Unknown	3.0 Years		Not Reported
Rate Abnormal; Swelling	Sulfate]							
	Sulfasalazine			S	Unknown	3.0 Years		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599531		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug	Xeljanz			S	Oral			Not Reported
Intolerance; Off Label Use;	Xeljanz			S	Oral			Not Reported
Rheumatoid Arthritis;	Adalimumab			S	Subcutaneous			Not Reported
Treatment Failure	Apo-Leflunomide			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Neoral	S	Oral	Not Reported
Neoral	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Actemra	S	Intravenous (not otherwise specified) 8mg/Kg	Not Reported
Rituximab	S	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810910	EXPEDITED (15-DAY)		OT	US-SA-2020SA128509			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Systemic Lupus Erythematosus	Dupixent			S	Unknown	Unk		Sanofi	
	Plaquenil			S				Sanofi	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810941	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600279		9 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Arthropathy; C-Reactive Protein Increased; Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Dispensing Error; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Cell Distribution Width Decreased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 01 Month		Not Reported	
	Rituximab			S				Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Tocilizumab			S				Not Reported	
	Adalimumab			S	Subcutaneous	Therapy Duration: 4 Years		Not Reported	
	Adalimumab			S				Not Reported	
	Enbrel			S	Subcutaneous	Therapy Duration: 609 Days		Not Reported	
	Enbrel			S				Not Reported	
	Etanercept			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Frequency: Cyclical		Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous	Therapy Duration: 5.0 Years		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Orencia			S				Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Abatacept			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810974	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601296		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Arthritis; Asthenia; Bone Erosion; C-Reactive Protein Abnormal; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gait Disturbance; Gastric Disorder; Gingival Bleeding; Headache; Hereditary Angioedema; Infection; Intentional Product Use Issue; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Mouth Haemorrhage; Musculoskeletal Stiffness; Nausea; Off Label Use; Peripheral Swelling; Rash; Syncope; Urticaria	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous	3.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	638.0		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral	7.0 Days		Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	C	Unknown	Not Reported
Prevacid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810976	EXPEDITED (15-DAY)	HO, OT		CA-ROCHE-2598434		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Actemra			S	Intravenous (not			Not Reported
Antibody Test Positive;					otherwise specified)			
Arthritis; Arthropathy;	Actemra			S	Intravenous (not			Not Reported
Body Height Below					otherwise specified)			
Normal; Bone Density	Tocilizumab			S	Unknown			Not Reported
Decreased; C-Reactive	Adalimumab			S	Subcutaneous			Not Reported
Protein Increased;	Anakinra			S	Subcutaneous			Not Reported
Condition Aggravated;	Anakinra			S	Subcutaneous			Not Reported
Diarrhoea; Dizziness;	Anakinra			S	Subcutaneous			Not Reported
Drug Ineffective; Drug	Anakinra			S	Subcutaneous			Not Reported
Intolerance; Drug Specific	Anakinra			S	Subcutaneous			Not Reported
Antibody; Human	Apo-Naproxen			S	Unknown			Not Reported
Antichimeric Antibody	Apo-Prednisone			S	Oral			Not Reported
Positive; Intentional	Apo-Prednisone			S	Oral			Not Reported
Product Use Issue; Joint	Enbrel			S	Subcutaneous			Not Reported
Effusion; Joint Injury;	Enbrel			S	Subcutaneous			Not Reported
Juvenile Idiopathic	Humira			S	Subcutaneous			Not Reported
Arthritis; Loss Of Personal	Hydroxychloroquine			S	Oral			Not Reported
Independence In Daily	Hydroxychloroquine			S	Oral			Not Reported
Activities; Mobility	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Decreased; Nausea;				S				Not Reported
Obesity; Off Label Use;				S				Not Reported
Polyarthritis; Psoriasis;				S				Not Reported
Red Blood Cell				S				Not Reported
Sedimentation Rate				S				Not Reported
Increased; Septic Shock;	Immunoglobulins			S	Intravenous (not			Not Reported
Synovitis; Vomiting;	[Immunoglobulins Nos]				otherwise specified)			
Wheelchair User	Immunoglobulins			S	Intravenous (not			Not Reported
	[Immunoglobulins Nos]				otherwise specified)			
	Infliximab			S	Intravenous (not			Not Reported
					otherwise specified)			

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Triamcinolone	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Triamcinolone Hexacetonide	S	Other	Not Reported
Naproxen	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17810997	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601428			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Asthma; Drug Ineffective; Encephalitis Viral; Infection; Lung Disorder; Retinal Deposits; Wheezing	Rituximab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811009	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601514		58 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Amino	Actemra			S	Unknown			Not Reported	
transferase Increased; Aspartate	Actemra			S	Unknown			Not Reported	
Amino	Rituximab			S	Unknown			Not Reported	
transferase Increased; Basal Cell	Codeine			S	Unknown			Not Reported	
Carcinoma; Blood	Enbrel			S	Unknown			Not Reported	
Parathyroid Hormone	Humira			S	Unknown			Not Reported	
Decreased; C-Reactive Protein	Hydroxychloroquine			S	Unknown			Not Reported	
Increased; Drug Eruption; Drug	Leflunomide			S	Unknown			Not Reported	
Hypersensitivity; Drug	Methotrexate			S	Subcutaneous			Not Reported	
Ineffective; Drug Tolerance	Methotrexate			S	Subcutaneous			Not Reported	
Decreased; Granuloma Skin;	Methotrexate			S	Subcutaneous			Not Reported	
Hypercalcaemia; Hypersensitivity;	Methotrexate			S	Unknown			Not Reported	
Inflammation; Infusion	Methotrexate			S	Unknown			Not Reported	
Related Reaction; Loss Of	Methotrexate			S	Unknown			Not Reported	
Personal Independence In	Methotrexate			S	Unknown			Not Reported	
Daily Activities; Panniculitis;	Orencia			S	Unknown			Not Reported	
Peripheral Swelling; Rash Pruritic;	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
Rheumatoid Arthritis; Rheumatoid	Sulfasalazine			S	Unknown			Not Reported	
Nodule; Skin Necrosis; Skin Ulcer	Alendronate Sodium			S	Unknown			Not Reported	
	Ciclosporin			C				Not Reported	
	Prednisone			C				Not Reported	
	Xeljanz			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599637		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Bone	Actemra			S	Unknown			Not Reported	
Erosion; Diabetes Mellitus; Drug	Arava			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity; Drug Ineffective; Erythema; Joint Swelling; Peripheral Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Negative; Skin Laceration; Skin Ulcer; Swelling; Treatment Failure	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811141	EXPEDITED (15-DAY)		OT	ES-ACCORD-182600		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
	Azithromycin			S	Oral	500 Mg Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811170	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601669		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Drug Intolerance; Intentional Product Use Issue;	Rituximab			S	Intravenous drip			Not Reported	
Nausea; Neutropenia; Off Label Use; Osteoarthritis; Platelet Count Decreased; Rheumatoid Arthritis;	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
Sinusitis; Skin Papilloma; Sleep Disorder; Synovitis; Thrombocytopenia; White Blood Cell Count	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased	Humira	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Actemra	C	Subcutaneous	Not Reported
	Advil [Ibuprofen]	C		Not Reported
	Arava	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Not Reported
	Ketorolac	C		Not Reported
	Naproxen	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811317	EXPEDITED (15-DAY)		HO	ES-ACCORD-182419		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Colchicine			S	Oral	1 U Breakfast		Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811320	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599199		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Cerebrovascular	Actemra			S	Unknown			Not Reported
Accident; Diverticular	Alendronate Sodium			S	Unknown			Not Reported
Perforation; Drug	Acetylsalicylic Acid			S	Unknown			Not Reported
Hypersensitivity; Drug	Calcium			S	Unknown			Not Reported
Intolerance; Insomnia;	Fosinopril			S	Unknown			Not Reported
Joint Swelling; Knee								
Arthroplasty; Pain;								
Peripheral Swelling;								

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Psoriasis; Psoriatic	Humira	S	Subcutaneous	Not Reported
Arthropathy; Rash; Skin	Methotrexate	S	Unknown	Not Reported
Reaction; Therapeutic	Morphine	S	Unknown	Not Reported
Product Effect Decreased;	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported
Therapeutic Product Effect	Sulfate]			
Incomplete	Simponi	S	Subcutaneous	Not Reported
	Synthroid	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811632	EXPEDITED (15-DAY)		OT	GB-ACCORD-182513		53 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Nausea	Hydroxychloroquine			S				Not Reported
	Colecalciferol			C		(Not Low Vit D)		Not Reported
	Fluoxetine			C				Not Reported
	Levothyroxine			C				Not Reported
	Cerazette			C				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811798	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599045			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Localised	Actemra			S	Unknown			Not Reported
Infection; Malaise;	Arava			S	Unknown			Not Reported
Pleurisy; Pneumonia	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811825	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238636			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Epistaxis; Headache; Insomnia; Nausea; Osteonecrosis Of Jaw; Transaminases Increased	Risedronate Sodium			S	Oral			Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S	Oral			Teva
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	300 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	50 Milligram Daily;		Not Reported
	Azathioprine			C	Oral	150 Milligram Daily;		Not Reported
	Azathioprine			C	Unknown			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Ketoprofen			C	Unknown			Not Reported
	Methotrexate			C	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Prolia Pre-Filled Preservative-Free			C	Subcutaneous			Not Reported
	Rituximab			C	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811925	EXPEDITED (15-DAY)		HO	CA-ADVANTZ PHARMA-202005005294			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Arava			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Cortisone			S	Unknown	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811929	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600700		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthritis; Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gastric Disorder; Gingival Bleeding; Headache; Infection; Joint Swelling; Liver Function Test Abnormal; Liver Function Test Increased; Loss Of Personal Independence In Daily Activities; Off Label Use; Rash; Syncope; Urticaria	Actemra Rituximab Arava Enbrel Humira Methotrexate Orencia Plaquenil [Hydroxychloroquine Sulfate] Remicade Simponi Prednisone Prevacid Xeljanz	S S S S S S S S S C C C	Unknown Intravenous drip Oral Subcutaneous Subcutaneous Unknown Intravenous (not otherwise specified) Unknown Intravenous (not otherwise specified) Subcutaneous Unknown Unknown Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811956	EXPEDITED (15-DAY)		DE, HO	ES-FRESENIUS KABI- FK202004819		72 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypofibrinogenaemia; Upper Gastrointestinal Haemorrhage	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	600 Mg Every 12 Hours		Fresenius Medical Care
	Meropenem (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	1 G Every 8 Hours		Not Reported
	Piperacillin/Tazobactam 4g / 0.5g (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	1 Df Every 8 Hours		Not Reported
	Tocilizumab			S				Not Reported
	Tocilizumab			S				Not Reported
	Metamizole			S	Intravenous (not otherwise specified)	2 G Every 8 Hours		Not Reported
	Hydroxychloroquine			S	Oral	400 Mg/Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17811963	EXPEDITED (15-DAY)		DE, OT	MX-ADVANZ PHARMA-202005005293			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use; Staphylococcal Infection	Hydroxychloroquine			S		200 Mg Every 12 Hours, Bid		Concordia	
	Hydroxychloroquine			S				Concordia	
	Clarithromycin			C				Not Reported	
	Ceftriaxone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601567		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Erythromycin			C	Unknown			Not Reported	
	Methotrexate			C	Oral			Not Reported	
	Morphine			C	Topical			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812011	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600095			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Disease	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not	8.0 Months		Not Reported	

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Recurrence; Drug Ineffective; Impaired Work Ability; Infection; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Off Label Use; Pain; Sleep Disorder Due To General Medical Condition, Insomnia Type	Arava	S	otherwise specified)		
	Enbrel	S	Unknown		Not Reported
	Gold	S	Subcutaneous	5.0 Months	Not Reported
	Humira	S	Unknown	7.0 Months	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Subcutaneous	7.0 Months	Not Reported
	Methotrexate	S	Unknown	3.0 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Sulfasalazine	S	Oral	5.0 Months	Not Reported
	Sulfasalazine	S	Oral	5.0 Months	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812069	EXPEDITED (15-DAY)		HO, LT, OT	FR-MYLANLABS-2020M1049048		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Cough; Covid-19; Headache; Intentional Product Misuse; Interstitial Lung Disease; Lung Opacity; Myalgia; Off Label Use; Pyrexia; Respiratory Failure	Prednisone			S		15 Mg Daily		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Four Infusions (375 Mg/M2) Were Weekly		Mylan
	Rituximab			S		Maintenance Therapy; 500 Mg		Mylan
	Hydroxychloroquine Sulfate			S		200 Mg/8 Hour For 10 Days From Day #19		Mylan
	Nebivolol			C		Unk		Mylan

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21-May-2020	17812115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598046			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812231	EXPEDITED (15-DAY)		DS, OT	MX-ADVANTZ PHARMA- 202005005296			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Depression; Hypoxia; Intentional Product Misuse; Pleural	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Qd		Concordia
	Hydroxychloroquine Sulfate			S	Unknown	1 Dosage Form, Qd		Concordia

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Effusion; Pyrexia; Visual Impairment (Authorized Generic),Plaquenil

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812256	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC-2020200777		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Off Label Use; Product Use In Unapproved Indication; Respiratory Failure; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Mg, Daily		Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported	
	Enoxaparine			S	Subcutaneous	80 Mg, Unknown		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812349	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020199194		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles; Ventricular Tachycardia	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Tazocilline			C		Unk		Not Reported	
	Vialebex			C		Unk		Not Reported	
	Paracetamol			C		Unk		Not Reported	
	Levothyroxine Sodium			C		Unk		Not Reported	
	Heparin Sodium			C		Unk		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Kardegic			C		75 Mg		Not Reported	
	Hypnovel [Midazolam]			C		Unk		Not Reported	

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	Hydrochloride]								
	Rapifen [Alfentanil		C			Unk			Not Reported
	Hydrochloride]								
	Sufenta		C			Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812441	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198949		73 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	1 Mg/Kg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	
	Roactemra			S		Unk		Not Reported	
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	2 Df, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812551	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020198926		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycine			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported	
	Irbesartan Eg			S	Oral	Unk		Not Reported	
	Carvedilol Arrow			S	Oral	Unk		Not Reported	
	Lasilix			S	Oral	Unk		Not Reported	
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812607	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049321		86 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir	S		Unk		Not Reported
	Hydroxychloroquine	S		Unk		Mylan
	Dabigatran	S	Oral	110 Mg/Day X 2		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812616	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049343		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported	
	Apixaban			S	Oral	5 Mg/Day X 2		Mylan	
	Hydroxychloroquine			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812622	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049342		69 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported	
	Hydroxychloroquine			S		Unk		Mylan	
	Apixaban			S	Oral	Unk(5 Mg/Day X 2)		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812625	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1049357		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Off Label Use	Lopinavir/Ritonavir			S	Oral	1000 Milligram, Total		Not Reported	
	Plaquenil /00072602/			S	Oral	400 Milligram, Total		Mylan	
	Roactemra			S	Intravenous (not otherwise specified)	704 Milligram, Total		Mylan	
	Inhixa			C		Unk		Mylan	
	Piperacillina/Tazobactam			C		13.5 Gram		Mylan	

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21-May-2020	17812626	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1049326		89 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Off Label Use	Lopinavir/Ritonavir			S		Unk		Not Reported	
	Apixaban			S	Oral	2.5 Mg/Day X 2		Mylan	
	Hydroxychloroquine			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812696	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131577		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi	
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Sanofi	
	Methotrexate			S	Unknown	20 Mg		Not Reported	
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported	
	Methotrexate			S	Unknown	200 Mg, Qw		Not Reported	
	Actemra			S	Unknown			Not Reported	
	Leflunomide			S	Oral	20 Mg, Qd		Sanofi	
	Enbrel			S	Unknown	25 Mg, Biw		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Q6w		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
	Wellbutrin			C	Oral			Not Reported	
	Xeljanz			C				Not Reported	

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21-May-2020	17812701	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131492			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Drug Intolerance; Lymphoma; Neoplasm Malignant; Onycholysis; Tooth Loss	Hydroxychloroquine Sulfate			S				Sanofi
	Leflunomide			S				Sanofi
	Methotrexate			S				Not Reported
	Sulfasalazine			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Orencia			S				Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Varicella Zoster Vaccine Live			S	Intravenous (not otherwise specified)			Not Reported
	Desoximetasone			C	Oral			Not Reported
	Diclofenac			C	Oral	100 Mg		Not Reported
	Xeljanz			C	Oral	5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812706	EXPEDITED (15-DAY)		DS, OT	CA-SA-2020SA131108			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Rheumatoid Arthritis; Stress	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Leflunomide			S	Unknown			Sanofi
	Mefenamic Acid			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Qw		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Tylenol	C			Not Reported
	Prednisone	C		Unk Unk, Qd	Not Reported
	Prednisone	C	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812765	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049416		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Plaquenil /00072603/			S	Oral	3 Dosage Form, Qd		Mylan	
	Lansoprazole			C	Oral	15 Milligram, Qd		Mylan	
	Tamiflu			C	Oral	2 Dosage Form, Qd		Mylan	
	Augmentin /00756801/			C	Intravenous (not otherwise specified)	3 Gram, Qd		Mylan	
	Lovenox			C	Subcutaneous	1 Dosage Form, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812844	EXPEDITED (15-DAY)		OT	ES-ALVOGEN-2020-ALVOGEN-108420		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Fentanyl			S				Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Oral	200mg/12h		Not Reported
	Kaletra	S	Oral	5 MI/12h		Not Reported
	Midazolam	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812879	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049499		64 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Tercian /00759301/			S	Oral	25 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Oral	200 Milligram, Bid		Mylan
	Paroxetine			C	Oral	30 Milligram, Qd		Mylan
	Depakine /00228501/			C	Oral	1000 Milligram, Qd		Mylan
	Aerius /01398501/			C	Oral	5 Milligram, Qd		Mylan
	Xanax			C	Oral	0.75 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812925	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599304		86 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypersensitivity; Off Label Use; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Subcutaneous	Not Reported
Remicade	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812965	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200515201		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Off Label Use	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813015	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601697		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Arthropathy; Drug Ineffective; Drug Intolerance; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Daily Activities; Migraine;	Humira	S	Subcutaneous	Not Reported
Mobility Decreased;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Nausea; Off Label Use;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Pain In Extremity;	Leflunomide	S	Unknown	Not Reported
Pneumonia; Pulmonary	Methotrexate	S	Oral	Not Reported
Fibrosis; Rheumatoid	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Arthritis; Rheumatoid	Prednisone	S	Unknown	Not Reported
Factor Positive; Synovitis;	Prednisone	S	Unknown	Not Reported
Therapeutic Product Effect	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Decreased; Vomiting; X-Ray Abnormal	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813024	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514324			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapy Non-Responder; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil /00072602/	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813034	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514312		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Drug Ineffective; Drug Intolerance; Pulmonary Fibrosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Gold			S	Intramuscular			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Sulfasalazine			S	Rectal			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813038	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600125		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Arava	S	Oral	Not Reported
Celebrex	C		Not Reported
Diclofenac	C		Not Reported
Lyrica	C		Not Reported
Methotrexate	C		Not Reported
Sulfasalazine	C		Not Reported
Valsartan	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813064	EXPEDITED (15-DAY)	OT		CA-ROCHE-2598767		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Actemra			S	Unknown			Not Reported
Drug Ineffective; Fatigue;	Humira			S	Subcutaneous			Not Reported
Liver Injury; Loss Of	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Personal Independence In	Leflunomide			S	Unknown			Not Reported
Daily Activities; Neck Pain;	Methotrexate			S	Unknown			Not Reported
Nodule; Pain; Pain In								
Extremity; Swelling								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine			S	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813177	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601625		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported	
Alopecia; Arthralgia; Drug	Rituxan			S	Intravenous (not			Not Reported	
Ineffective;					otherwise specified)				
Hypersensitivity; Joint	Apo-Prednisone			S	Unknown			Not Reported	
Swelling; Maternal	Arava			S	Unknown			Not Reported	
Exposure During	Cetirizine Hydrochloride			S	Unknown			Not Reported	
Pregnancy;	Cetirizine			S	Unknown			Not Reported	
Musculoskeletal Stiffness;	Hydrochloride;Pseudoephedrine								
Off Label Use; Pain;	Hydrochloride								
Pemphigus; Pericarditis;	Cimzia			S	Subcutaneous			Not Reported	
Product Use Issue;	Cortisone Acetate			S	Unknown			Not Reported	
Rheumatoid Arthritis;	Cortisone Acetate			S	Unknown			Not Reported	
Systemic Lupus	Enbrel			S	Subcutaneous			Not Reported	
Erythematous;	Folic Acid			S	Unknown			Not Reported	
Therapeutic Product Effect	Fosamax			S	Unknown			Not Reported	
Decreased; Treatment	Golimumab			S	Unknown			Not Reported	
Failure	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Intravenous (not			Not Reported	
					otherwise specified)				
	Phthalylsulfathiazole			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfate]				
Prednisone	S	Unknown		Not Reported
Prednisone	S			Not Reported
Pseudoephedrine Hcl	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Diclofenac	C	Unknown		Not Reported
Salazopyrin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813252	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020198921		71 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Feeling Hot; Flushing; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Senile Pruritus; Skin Exfoliation; Skin Reaction	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, 1x/Day		Not Reported
	Rezolsta			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813289	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600406		54 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Asthenia; C-Reactive	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Protein Increased; Cataract; Constipation; Drug Ineffective; Fatigue; Hepatic Cirrhosis; Herpes Zoster; Joint Injury; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813295	EXPEDITED (15-DAY)		OT	ES-MYLANLABS- 2020M1049663		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Tinnitus	Fentanyl			S		Unk		Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)	Unk		Mylan
	Ceftriaxona /00672201/			S	Intravenous (not otherwise specified)	Unk		Mylan
	Kaletra			S	Oral	5 Milliliter, Bid (5 MI/12h)		Mylan
	Midazolam			S		Unk		Mylan
	Hidroxiclороquina /00072601/			S	Oral	200 Milligram, Bid (200mg/12h)		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813311	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235960		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Embolism	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Privigen 100mg/MI Solucion Para Perfusion , 1 Vial De 400 MI			S	Intravenous (not otherwise specified)			Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813329	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1236090		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported	
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	75 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813343	EXPEDITED (15-DAY)		OT	NVSC2020US140080			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress	Hydroxychloroquine			S	Unknown	Unk		Novartis	

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Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin	S	Unknown	Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813420	NON-EXPEDITED			US-PFIZER INC- 2020197950			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Off Label Use; Product Use In Unapproved Indication	Zinecard			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813445	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1049616		48 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tachycardia	Amlodipine Besilate/Valsartan			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	400 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813449	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1238634		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection; Nausea; Nodule; Rheumatoid Arthritis	Risedronate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

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Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813842	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20200518237		55 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use In Unapproved Indication; Tinnitus	Durogesic Matrix			S	Unknown			Janssen
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Kaletra			S	Oral	5 MI/12h		Not Reported
	Midazolam			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral	200mg/12h		Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17814201	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602587			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease; Joint Swelling; Treatment Failure	Rituximab			S	Intravenous drip			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Sulfasalazine			S	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17814262	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238635		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Drug Ineffective; Drug Intolerance; Nausea; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Synovitis	Risedronate Sodium			S	Unknown			Teva	
	Risedronate Sodium			S	Oral			Teva	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Oral	20 Milligram Daily;		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquinesulfate			S	Unknown			Not Reported	
	Hydroxychloroquinesulfate			S	Oral	300 Milligram Daily;		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17814270	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238637		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional	Risedronate Sodium			S	Unknown			Teva	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	

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Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Off Label Use; Pulmonary Fibrosis; Rheumatoid Factor Positive; Synovitis	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Oral	20 Milligram Daily;	Not Reported
	Cimzia Single-Use Prefilled Syringe	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Gold	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	300 Milligram Daily;	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	10653444	EXPEDITED (15-DAY)		DS	FR-009507513-1412FRA006146		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Fosamax			S	Oral	Unk		Merck
	Lasilix			S	Oral	Unk		Not Reported
	Plaquenil			S	Oral	Unk		Not Reported
	Lexomil			S	Oral	Unk		Not Reported
	Cacit Vitamine D3			S	Oral	Unk		Not Reported
	Rivotril			S	Oral	Unk		Not Reported
	Avodart			S	Oral	Unk		Not Reported
	Cymbalta			S	Oral	Unk		Not Reported
	Inexium (Esomeprazole)			S	Oral	Unk		Not Reported

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Magnesium) Salazopyrine	S	Oral	Unk	Not Reported
Tahor	S	Oral	Unk	Not Reported
Forlax	S	Oral	Unk	Not Reported
Skenan	S	Oral	Unk	Not Reported
Cortancyl	S	Oral	Unk	Not Reported
Metoject	S	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	11385922	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-ROCHE-1619365		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Actemra			S	Unknown			Not Reported
Arthropathy; C-Reactive	Actemra			S				Not Reported
Protein Abnormal; C-	Rituxan			S	Unknown			Not Reported
Reactive Protein	Rituxan			S				Not Reported
Increased;	Methotrexate			S	Unknown			Not Reported
Contraindicated Product	Methotrexate			S	Intra-arterial			Not Reported
Administered; Death;	Leflunomide			S	Unknown			Not Reported
Deep Vein Thrombosis;	Leflunomide			S	Oral			Not Reported
Diverticulitis; Drug	Sulfasalazine			S	Unknown			Not Reported
Hypersensitivity; Drug	Sulfasalazine			S	Unknown			Not Reported
Ineffective; Drug	Anakinra			S	Unknown			Not Reported
Intolerance; Feeling	Anakinra			S	Unknown			Not Reported
Abnormal; Herpes Zoster;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Intentional Product Use	Hydroxychloroquine Sulfate			S				Not Reported
Issue; Interstitial Lung	Humira			S	Subcutaneous			Not Reported
Disease; Joint Swelling;	Humira			S	Unknown			Not Reported
Off Label Use; Pain;	Orencia			S	Intravenous (not			Not Reported
Photosensitivity Reaction;					otherwise specified)			
Product Use In	Orencia			S	Intravenous (not			Not Reported
Unapproved Indication;								
Pulmonary Embolism;								
Pulmonary Thrombosis;								
Red Blood Cell								
Sedimentation Rate								
Increased; Renal Failure;								
Rheumatoid Arthritis;								

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Sepsis; Stomatitis; Thrombosis; Urticaria				otherwise specified)	
	Plaquenil [Hydroxychloroquine Sulfate]	S		Unknown	Not Reported
	Enbrel	S		Subcutaneous	Not Reported
	Enbrel	S		Unknown	Not Reported
	Remicade	S		Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine	S		Unknown	Not Reported
	Hydroxychloroquine	S		Unknown	Not Reported
	Arava	S		Oral	Not Reported
	Arava	S			Not Reported
	Sodium Aurothiomalate	S		Intramuscular	Not Reported
	Apo-Leflunomide	S		Unknown	Not Reported
	Apo-Leflunomide	S			Not Reported
	Cannabis Sativa	S		Unknown	Not Reported
	Gold	S		Unknown	Not Reported
	Gold	S			Not Reported
	Ilaris	S		Subcutaneous	Not Reported
	Ilaris	S		Unknown	Not Reported
	Minocycline	S		Unknown	Not Reported
	Minocycline Hydrochloride	S		Unknown	Not Reported
	Oxycodone	S		Unknown	Not Reported
	Oxyquinoline Sulfate	S		Unknown	Not Reported
	Oxyquinoline Sulfate	S			Not Reported
	Lyrica	C		Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	11565068	EXPEDITED (15-DAY)		DS, LT, OT	CA-009507513-1509CAN012569			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Abdominal Discomfort;	Fosamax	S	Oral	Unk	Merck
Abdominal Pain;	Fosamax	S		Route: Intra Corpus	Merck
Abdominal Pain Upper;				Cavernosum	
Adverse Drug Reaction;	Fosamax	S	Unknown	Unk	Merck
Adverse Event; Alopecia;	Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Anti-Cyclic Citrullinated	Methotrexate	S	Intra-arterial	25 Mg, 1 Every 1 Week(S)	Not Reported
Peptide Antibody Positive;	Methotrexate	S	Unknown	Unk	Not Reported
Arthralgia; Arthropathy;	Methotrexate	S	Oral	Unk, Qd	Not Reported
Blister; Condition	Methotrexate	S	Unknown	20.0 Milligram, 1 Every 1	Not Reported
Aggravated;	Methotrexate	S	Oral	Days; Solution	Not Reported
Contraindicated Product	Methotrexate	S	Oral	25.0 Milligram	Not Reported
Administered; Diarrhoea;	Methotrexate	S	Unknown	25.0 Milligram	Not Reported
Discomfort; Dizziness;	Methotrexate	S	Oral	20.0 Milligram, 1 Every 1	Not Reported
Drug Ineffective; Drug	Methotrexate	S	Oral	Days	Not Reported
Intolerance; Duodenal	Methotrexate	S	Intra-arterial	25 Unk	Not Reported
Ulcer Perforation;	Methotrexate	S	Intravenous (not	Powder For Solution	Not Reported
Exposure During	Methotrexate	S	otherwise specified)	Unk; Solution	Not Reported
Pregnancy; Fatigue;	Methotrexate	S	Subcutaneous	Subcutaneous	Not Reported
Fibromyalgia; General	Methotrexate	S	Unknown	5 Milligram	Not Reported
Physical Health	Methotrexate	S	Unknown	Unk	Not Reported
Deterioration;	Remicade	S	Unknown	1 Milligram	Not Reported
Glossodynia; Hand	Simponi	S	Subcutaneous	50 Milligram, Qw	Not Reported
Deformity; Helicobacter	Apo Prednisone	S	Subcutaneous	Unk	Not Reported
Infection; Hepatic Enzyme	Apo Prednisone	S	Subcutaneous	Unk	Not Reported
Increased; Hip	Apo Prednisone	S	Oral	20 Milligram, Unknown	Not Reported
Arthroplasty;	Enbrel	S	Unknown	Unk	Not Reported
Hypersensitivity; Infusion	Enbrel	S	Unknown	Unk	Not Reported
Related Reaction; Injury;	Enbrel	S	Unknown	Unk	Not Reported
Intentional Product Use	Enbrel	S	Unknown	Unk	Not Reported
Issue; Joint Swelling;	Enbrel	S	Unknown	Unk	Not Reported
Knee Arthroplasty; Live	Enbrel	S	Unknown	Unk	Not Reported
Birth; Maternal Exposure	Enbrel	S	Unknown	Unk	Not Reported
During Pregnancy;	Enbrel	S	Unknown	Unk	Not Reported
Musculoskeletal Stiffness;	Enbrel	S	Unknown	Unk	Not Reported
Nausea; Oedema; Off	Enbrel	S	Unknown	Unk	Not Reported
Label Use; Pain;	Enbrel	S	Unknown	Unk	Not Reported
Pemphigus; Pericarditis;	Enbrel	S	Unknown	Unk	Not Reported
Prescribed Overdose;	Enbrel	S	Unknown	Unk	Not Reported
Product Use Issue; Rash;	Enbrel	S	Unknown	Unk	Not Reported
Rheumatoid Arthritis;	Enbrel	S	Unknown	Unk	Not Reported
Rheumatoid Factor	Enbrel	S	Unknown	Unk	Not Reported
Positive; Swelling;	Enbrel	S	Unknown	Unk	Not Reported

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Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; Wheezing; Wound	Humira	S	Subcutaneous	40 Mg/0.8 MI, Solution For Injection In Prefilled Syringe	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Orencia	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Plaquenil	S	Oral	400 Mg, 1 Every 1 Day(S)	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, 2 Every 1 Day(S)	Not Reported
	Sulfasalazine	S	Unknown	500 Milligram, Unknown	Not Reported
	Apo Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Apo Folic Acid	S	Unknown	1, Unk	Not Reported
	Apo Folic Acid	S	Unknown	15 Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Phthalylsulfathiazole	S			Not Reported
	Zyrtec	S	Unknown	25 Milligram	Not Reported
	Cortisone	S	Unknown	Unk	Not Reported
	Cortisone	S	Oral	Unk	Not Reported
	Apo Hydroxyquine	S	Unknown	400 Mg, Q24h	Not Reported
	Desoximetasone	S	Oral	Unk; Dosage Form: Not Specified	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Desoximetasone	S	Cutaneous	Unk	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram, Qd	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Milligram, Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported

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Pseudoephedrine Hydrochloride	S	Unknown	25 Milligram	Not Reported
Diclofenac Sodium	S	Unknown	Unk; Dosage Form Not Specified	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	25.0 Milligram	Not Reported
Cetirizine Hydrochloride (+) Pseudoephedrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Subcutaneous	Unk	Not Reported
Topicort (Hydrocortisone Acetate)	S	Unknown	Unk, Other	Not Reported
Topicort (Hydrocortisone Acetate)	S	Cutaneous	Unk; Dosage Form Not Specified	Not Reported
Folic Acid	S	Oral	500 Milligram Per Litre, Unknown	Not Reported
Folic Acid	S	Unknown	1.0 Milligram, Unknown	Not Reported
Folic Acid	S	Unknown	5.0 Milligram	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk, Unknown	Not Reported
Hydroxychloroquine Sulfate	S		400 Milligram, Qd	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	4000.0 Milligram, 1 Every 1 Days	Not Reported
Prednisone	S	Unknown	Unk; Dosage Form: Not Specified	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2 Every 1 Days	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported
Acetaminophen	S	Unknown	Unk, Unknown	Not Reported

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Tofacitinib Citrate	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride (+) Phenylephrine Hydrochloride	S	Unknown	10.0 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Oral	Unk	Not Reported
Topicort (Desoximetasone)	S	Other	Unk	Not Reported
Topicort (Desoximetasone)	S	Subcutaneous	Unk	Not Reported
Certolizumab Pegol	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Atasol (Acetaminophen)	C	Unknown	Unk	Not Reported
Atasol (Acetaminophen)	C			Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Prinivil	C	Unknown	Unk	Merck
Cholecalciferol	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Zyrtec	C	Unknown	Unk	Not Reported
Tofacitinib	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	12321013	EXPEDITED (15-DAY)		OT	CA-ROCHE-1745426		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Anti-Cyclic	Actemra			S	Subcutaneous			Not Reported
Citrullinated Peptide	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Antibody Positive;	Arava			S	Oral			Not Reported
Arthropathy; Condition								
Aggravated;								
Contraindicated Product								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Administered; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Knee Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia Enbrel Enbrel Folic Acid Folic Acid Fosamax Humira Humira Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Orencia Orencia Phthalylsulfathiazole Plaquenil [Hydroxychloroquine Sulfate] Plaquenil [Hydroxychloroquine Sulfate] Apo-Prednisone Apo-Prednisone Reactine [Cetirizine Hydrochloride] Reactine [Cetirizine Hydrochloride] Reactine [Cetirizine Hydrochloride] Simponi Cetirizine Hydrochloride Cortisone Acetate	S S S S S S S S S S S S S S S S S S S S S S S S S S	Subcutaneous Subcutaneous Unknown Unknown Unknown Oral Subcutaneous Subcutaneous Unknown Oral Oral Oral Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Subcutaneous Unknown Unknown	Single Use As Prefilled Syring	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Acetaminophen	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	12422597	EXPEDITED (15-DAY)		OT	CA-ROCHE-1766629		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition	Actemra			S	Subcutaneous			Not Reported
Aggravated; Contraindicated Product	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Administered; Drug	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
Hypersensitivity; Drug	Sulfasalazine			S	Unknown			Not Reported
Hypersensitivity; Drug	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Ineffective; Drug	Orencia			S	Unknown			Not Reported
Intolerance; Drug	Simponi			S	Subcutaneous			Not Reported
Intolerance; Joint Swelling;	Arava			S	Unknown			Not Reported
Multiple Allergies;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Musculoskeletal Pain;				S	Unknown			Not Reported
Psoriatic Arthropathy;	Enbrel			S	Subcutaneous			Not Reported
Rash; Rash; Red Blood	Humira			S	Unknown			Not Reported
Cell Sedimentation Rate	Methotrexate Sodium			S	Unknown			Not Reported
Increased; Rheumatoid	Lyrica			S	Oral			Not Reported
Arthritis; Sciatica;	Hydroxychloroquine			S	Unknown			Not Reported
Sinusitis; Sinusitis;								
Swelling; Therapeutic								
Product Effect Incomplete;								
Treatment Failure								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Piroxicam	S	Unknown	Not Reported
Prednisone	S	Urethral	Not Reported
Prednisone	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Cimzia	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Morphine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	12842578	EXPEDITED (15-DAY)		DS, OT	CA-ORION CORPORATION ORION PHARMA-TREX2016- 1958		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Inappropriate Schedule Of Product Administration; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Pantoloc			S	Unknown			Not Reported
	Pantoloc			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo Folic Acid	S	Unknown	Twice In A Week	Not Reported
Apo Folic Acid	S	Unknown	Twice A Week	Not Reported
Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Naprosyn	S	Oral		Not Reported
Palafer Cf	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Arava	S	Unknown		Not Reported
Arava	S	Oral		Not Reported
Arava	S	Oral		Not Reported
Enbrel	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown		Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Abatacept	S	Unknown		Not Reported
Ascorbic Acid	S	Unknown		Not Reported
Ferrous Fumarate	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Unknown	2/Week	Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	S	Unknown		Not Reported
Ferrous Fumarate-Folic Acid	S	Unknown		Not Reported
Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Naproxen	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Atenolol	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Unknown		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Naproxen Sodium	S	Oral		Not Reported
Etanercept	S	Unknown		Not Reported
Palafer	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Sodium	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown		Not Reported
Pantoprazole Teva	S	Unknown		Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ferrous Fumarate;Folic Acid	S	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Celecoxib	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	12922824	EXPEDITED (15-DAY)		OT	CA-ROCHE-1849821		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Adverse Event;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Anaphylactic Reaction; Arthralgia; Blood Glucose	Mycophenolate Mofetil			S	Unknown			Not Reported
Increased; Condition	Actemra			S	Unknown			Not Reported
Aggravated; Drug	Actemra			S	Subcutaneous			Not Reported
Hypersensitivity; Drug	Arava			S	Unknown			Not Reported
Ineffective; Drug	Arava			S	Oral			Not Reported
Intolerance; Joint Swelling; Multiple Allergies;	Enbrel			S	Unknown			Not Reported
Musculoskeletal Pain; Off	Enbrel			S	Subcutaneous			Not Reported
Label Use; Pain; Psoriatic	Humira			S	Subcutaneous			Not Reported
Arthropathy; Rash; Red	Humira			S	Subcutaneous			Not Reported
Blood Cell Sedimentation	Lyrica			S	Oral			Not Reported
Rate Increased;	Orencia			S	Unknown			Not Reported
Rheumatic Disorder;	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Rheumatoid Arthritis;	Sulfate]			S	Unknown			Not Reported
Sciatica; Sinusitis;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Swelling; Swelling;	Simponi			S	Subcutaneous			Not Reported
Therapeutic Product Effect	Sulfasalazine			S	Unknown			Not Reported
Incomplete; Therapeutic	Sulfasalazine			S	Unknown			Not Reported
Product Effect Incomplete;	Methotrexate Sodium			S	Intra-arterial			Not Reported
Treatment Failure; Weight	Hydroxychloroquine			S	Unknown			Not Reported
Increased	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Pregabalin	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Urethral	Not Reported
Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Piroxicam	C	Unknown	Not Reported
Levothyroxine	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	13015664	EXPEDITED (15-DAY)		OT	CA-ROCHE-1865625		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enbrel	S	Subcutaneous	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Arava	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Imuran [Azathioprine]	S	Unknown	Not Reported
Cimzia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	13237837	EXPEDITED (15-DAY)		OT	CA-ROCHE-1893817		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasia; Synovitis; Tooth Loss	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Unknown	Not Reported
Zostavax	S	Subcutaneous	Not Reported
Varicella Zoster Vaccine Live	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Unknown	Not Reported
Apo-Hydroxyquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Subcutaneous	Not Reported
Desoximetasone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Subcutaneous	Not Reported
Voltaren [Diclofenac]	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	13538108	EXPEDITED (15-DAY)	OT		CA-ROCHE-1933679			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rituximab			S	Unknown			Not Reported
Acne Cystic; Condition	Anakinra			S	Unknown			Not Reported
Aggravated;	Apo-Hydroxyquine			S	Unknown			Not Reported
Contraindicated Product	Apo-Hydroxyquine			S	Unknown			Not Reported
Administered; Drug	Arava			S	Oral			Not Reported
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Incorrect	Humira			S	Subcutaneous			Not Reported
Route Of Product	Methotrexate			S	Oral			Not Reported
Administration; Insomnia;	Methotrexate			S	Subcutaneous			Not Reported
Rheumatoid Arthritis	Orencia			S	Unknown			Not Reported
	Orencia			S	Endocervical			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vioxx	S	Unknown	Not Reported
Naprosyn [Naproxen]	S	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	13614636	EXPEDITED (15-DAY)	DS		CA-ROCHE-1942553			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Rituxan			S	Intravenous (not			Not Reported
Alopecia; Anti-Cyclic					otherwise specified)			
Citrullinated Peptide	Actemra			S	Unknown			Not Reported
Antibody Positive;	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
Arthropathy; Condition	Arava			S	Oral			Not Reported
Aggravated;	Cortisone Acetate			S	Unknown			Not Reported
Contraindicated Product	Cortisone Acetate			S	Unknown			Not Reported
Administered; Discomfort;	Enbrel			S	Subcutaneous			Not Reported
Drug Ineffective; Drug	Folic Acid			S	Unknown			Not Reported
Intolerance; Duodenal	Fosamax			S	Unknown			Not Reported
Ulcer Perforation; Fatigue;	Methotrexate			S	Unknown			Not Reported
Glossodynia; Hand	Methotrexate			S	Oral			Not Reported
Deformity; Helicobacter	Methotrexate			S	Oral			Not Reported
Infection; Hepatic Enzyme	Orencia			S	Intravenous (not			Not Reported
Increased; Hip					otherwise specified)			
Arthroplasty;	Phthalylsulfathiazole			S	Unknown			Not Reported
Hypersensitivity; Infusion	Prednisone			S	Unknown			Not Reported
Related Reaction; Joint	Reactine [Cetirizine			S	Unknown			Not Reported
Swelling; Knee	Hydrochloride]							
Arthroplasty; Maternal	Remicade			S	Intravenous (not			Not Reported
Exposure During					otherwise specified)			
Pregnancy; Pain;	Simponi			S	Subcutaneous			Not Reported
Pemphigus; Pericarditis;								
Product Use Issue; Rash;								
Rheumatoid Arthritis;								
Rheumatoid Factor								
Positive; Swelling;								
Synovitis; Systemic Lupus								
Erythematous; Treatment								
Failure; Wound								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alendronate Sodium	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride;Ibuprofen;Phenylephrine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride;Ibuprofen;Phenylephrine Hydrochloride	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Desoximetasone	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Golimumab	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Kevzara	S	Subcutaneous	Not Reported
Leflunomide	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Topicorte	S	Subcutaneous	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
Salazopyrina	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	13628309	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20170602995		53 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Infection; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Decreased; Therapy Non- Responder	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Avara	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine

C

Oral

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	14267213	EXPEDITED (15-DAY)		OT	CA-ROCHE-2032902		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition	Actemra			S	Subcutaneous			Not Reported
Aggravated;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product								
Administered; Drug	Cellcept [Mycophenolate Mofetil]			S	Unknown			Not Reported
Hypersensitivity; Drug	Arava			S	Unknown			Not Reported
Intolerance; Joint Swelling;	Arava			S	Oral			Not Reported
Multiple Allergies;	Enbrel			S	Subcutaneous			Not Reported
Musculoskeletal Pain; Off	Lyrica			S	Oral			Not Reported
Label Use; Pain; Psoriatic	Methotrexate Sodium			S	Unknown			Not Reported
Arthropathy; Rash; Red	Orencia			S	Unknown			Not Reported
Blood Cell Sedimentation	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
Rate Increased;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Rheumatic Disorder;								
Rheumatoid Arthritis;	Simponi			S	Subcutaneous			Not Reported
Sciatica; Sinusitis;	Sulfasalazine			S	Unknown			Not Reported
Swelling; Therapeutic	Humira			S	Subcutaneous			Not Reported
Product Effect Incomplete;	Hydroxychloroquine			S	Unknown			Not Reported
Therapeutic Product Effect	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Incomplete; Treatment	Methotrexate			S	Intra-arterial			Not Reported
Failure	Cimzia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Gold			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

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	Mycophenolate Mofetil Hydrochloride	S	Unknown	Not Reported
	Mycophenolate Mofetil Hydrochloride	S	Subcutaneous	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Morphine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	14535557	EXPEDITED (15-DAY)	CA, OT		CA-BIOVITRUM-2018CA0126			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Anakinra			S	Subcutaneous			Not Reported
Acne Cystic; Condition	Arava			S	Oral			Not Reported
Aggravated;	Enbrel			S	Unknown	2 Every 1 Weeks 1 Every 2 Weeks		Not Reported
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Incorrect Route Of Product	Humira			S	Subcutaneous			Not Reported
Administration; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Naprosyn			S	Oral			Not Reported
	Naprosyn			S	Unknown			Not Reported
	Orencia			S	Endocervical			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Naproxen			S				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	14539306	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0138		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Joint Swelling; No Adverse Event; Renal Impairment; Therapeutic Product Effect Incomplete	Kineret			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Apo Hydroxychloroquine			S				Not Reported	
	Apo-Leflunomide			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Imuran			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Plaquenil			S				Not Reported	
	Apo-Azathioprine			S				Not Reported	
	Gold			S	Intramuscular			Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S				Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	14788235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2108819		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthropathy; Condition	Rituxan			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Gait Disturbance; Ill- Defined Disorder; Lung Disorder; Lupus-Like Syndrome; Musculoskeletal Stiffness; Pain; Quality Of Life Decreased; Rheumatoid Arthritis; Therapy Non- Responder; Tuberculin Test Positive	Rituxan	S	otherwise specified)	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Celecoxib	S	Oral		Not Reported
	Celecoxib	S	Oral		Not Reported
	Celecoxib	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituxan	S	Unknown		Not Reported
	Toradol	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Tramadol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15049785	EXPEDITED (15-DAY)		HO	CA-ROCHE-2141880		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired	Actemra			S	Unknown			Not Reported
	Aleve			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Healing; Intentional	Methotrexate	S	Unknown	Not Reported
Product Use Issue; Joint	Methotrexate Sodium	S	Unknown	Not Reported
Laxity; Limb Deformity;	Orencia	S	Unknown	Not Reported
Loose Body In Joint;	Prednisone Acetate	S	Unknown	Not Reported
Multiple Fractures; Off	Xeljanz	S	Oral	Not Reported
Label Use; Osteoporosis;	Apo-Leflunomide	S	Unknown	Not Reported
Osteoporotic Fracture;	Apo-Naproxen	S	Unknown	Not Reported
Pain; Rash; Red Blood	Apo-Prednisone	S	Unknown	Not Reported
Cell Sedimentation Rate	Novo-Prednisone	S	Unknown	Not Reported
Abnormal; Synovitis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Folic Acid	C	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15157332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2155675			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Fissure; Arthralgia;	Rituxan			S	Intravenous drip	Solution Intravenous		Not Reported
Bronchitis; C-Reactive	Arava			S	Oral			Not Reported
Protein Increased;	Orencia			S	Intravenous (not			Not Reported
Diarrhoea; Drug					otherwise specified)			
Ineffective; Drug	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
Intolerance; Dyspepsia;	Sulfasalazine			S	Unknown			Not Reported
Fear; Joint Swelling;	Enbrel			S	Subcutaneous			Not Reported
Laboratory Test Abnormal;	Xeljanz			S	Oral			Not Reported
Mucosal Inflammation; Off	Xeljanz			S	Unknown			Not Reported
Label Use; Pneumonia;	Actemra			S	Unknown			Not Reported
Pneumonia; Treatment	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Failure								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15369246	EXPEDITED (15-DAY)		OT	CA-ROCHE-2181844		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Contraindicated Product Administered; Joint Swelling; Pneumonia; Pneumonia; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringemide		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cephalexin [Cefalexin]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15372794	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2182468			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Contraindicated Product	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Administered; Drug	Actemra	S	Unknown	Not Reported
Ineffective; Hepatic	Enbrel	S	Subcutaneous	Not Reported
Enzyme Increased; Off	Humira	S	Subcutaneous	Not Reported
Label Use; Pneumonia;	Humira	S	Unknown	Not Reported
Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Simponi	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Prednisone	C		Not Reported
	Arava	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15470572	EXPEDITED (15-DAY)		OT	PHHY2016CA163833		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Sandostatin			S	Subcutaneous	50 Ug, Once/Single (Test Dose)		Novartis
Arthralgia; Arthritis; Blood Glucose Abnormal; Blood Pressure Increased;	Sandostatin Lar			S	Intramuscular	30 Mg, Qmo		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial Neuralgia; Fatigue; Groin Pain; Headache; Hypotension; Inappropriate Schedule Of Product Administration; Joint Stiffness; Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting	Sandostatin Lar Atorvastatin Bisoprolol Plaquenil Forxiga	S S S S C	Intramuscular Unknown Unknown Unknown Unknown	30 Mg, Qmo 10 Mg, Qd 2.5 Mg, Bid 200 Mg, 2 Tablets Once A Day 5 Mg, Qd	Novartis Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15476259	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP022037			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthralgia; Colitis; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Haematochezia; Joint Swelling; Pain In Extremity; Peripheral Swelling; Vitamin D Deficiency	Amlodipine Asacol Enbrel Enbrel Enbrel Humira Methotrexate Orencia Plaquenil /00072602/ Amlodipine Besilate Atacand Plus Bisoprolol Fumarate Depo-Medrol Ferrous Gluconate Folic Acid			S S S S S S S S S C C C C C C	Oral Oral Subcutaneous Unknown Unknown Subcutaneous Subcutaneous Unknown Oral Unknown Unknown Unknown Intra-articular Unknown Unknown	5 Mg, Qd 800 Mg, Tid 50 Mg, Unk 50 Mg, Unk 50 Mg, Unk Unk 25 Mg, Q.Wk. Unk Unk Unk Unk Unk Unk Unk		Apotex Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omega Allergenic Extracts	C	Unknown	Unk	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15615412	EXPEDITED (15-DAY)		DS, LT, OT	CA-APOTEX-2016AP016280			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Apo Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
Abdominal Pain Upper;	Apo Folic Acid			S	Unknown	15 Mg, Unk		Not Reported
Adverse Drug Reaction;	Apo-Hydroxyquine			S	Unknown	400 Mg, Qd		Apotex
Adverse Event; Alopecia;	Apo Prednisone Tab 1mg Usp			S	Unknown	Unk		Apotex
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Diclofenac			S	Unknown	Unk		Apotex
Arthralgia; Arthropathy;	Prednisone			S	Unknown	400 Mg, Unk		Apotex
Blister; Condition	Prednisone			S	Unknown	1 Mg, Unk		Apotex
Aggravated; Discomfort;	Prednisone			S	Oral	Unk		Apotex
Drug Ineffective; Drug	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
Intolerance; Duodenal	Hydroxychloroquine			S	Unknown	Unk		Apotex
Ulcer Perforation; Fatigue;	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
General Physical Health	Hydroxychloroquine			S	Oral	Unk		Apotex
Deterioration;	Hydroxychloroquine			S	Oral	Unk		Apotex
Glossodynia; Hand	Hydroxychloroquine			S	Oral	400 Mg, Qd		Apotex
Deformity; Helicobacter	Hydroxychloroquine			S	Oral	Unk		Apotex
Infection; Hepatic Enzyme	Hydroxychloroquine			S	Urethral	400 Mg, Qd		Apotex
Increased; Hip	Cetirizine			S	Unknown	10 Mg, Unk		Apotex
Arthroplasty;	Cetirizine			S	Unknown	Unk		Apotex
Hypersensitivity; Infusion	Cetirizine			S	Oral	10 Unk, Unk		Apotex
Related Reaction; Injury;	Cetirizine			S	Unknown	10 Mg, Qd		Apotex
Intentional Product Use	Cetirizine			S	Unknown	25 Mg, Unk		Apotex
Issue; Joint Swelling;	Apo-Prednisone			S	Unknown	1 Mg, Unk		Apotex
Knee Arthroplasty; Live	Apo-Prednisone			S	Unknown	5 Mg, Unk		Apotex
Birth; Maternal Exposure	Apo-Prednisone			S	Oral	Unk		Apotex
During Pregnancy;								
Musculoskeletal Stiffness;								
Off Label Use; Pain;								
Pemphigus; Pericarditis;								
Rash; Rheumatoid								
Arthritis; Rheumatoid								

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Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Therapeutic Product Effect Decreased; Treatment Failure; Wheezing; Wound	Acetaminophen	S	Unknown	Unk	Apotex
	Folic Acid	S	Unknown	1 Unk, Unk	Not Reported
	Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
	Folic Acid	S	Oral	25 Mg, Unk	Not Reported
	Folic Acid	S	Unknown	500 Mg, Unk	Not Reported
	Folic Acid	S	Oral	5 Mg, Unk	Not Reported
	Folic Acid	S	Oral	1 Mg, Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Apotex
	Leflunomide	S	Oral	Unk	Apotex
	Alendronate	S	Oral	Unk	Apotex
	Actemra	S	Subcutaneous	Unk	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Oral	Unk	Not Reported
	Arava	S	Oral	20 Mg, Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 G, Bid	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	1 Df, Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	1 G, Bid	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Sulfasalazine	S	Oral	1000 Mg, Bid	Not Reported
	Desoximetason	S	Oral	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Desoximetasone	S	Cutaneous	Unk	Not Reported
Desoximetasone	S	Unknown	25 Mg, Unk	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Fosamax	S	Oral	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Humira	S	Sunconjunctival	40 Mg, Unk	Not Reported
Humira	S	Sunconjunctival	Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Mg, Unk	Not Reported
Methotrexate	S	Intra-arterial	25 Unk, Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Intracardiac	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Phthalylsulfathiazole	S	Oral	500 Mg, Unk	Not Reported
Phthalylsulfathiazole	S	Oral	1000 Mg, Bid	Not Reported
Plaquenil /00072602/	S	Unknown	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk Unk, Qd	Not Reported
Plaquenil /00072602/	S	Unknown	400 Unk, Unk	Not Reported
Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
Plaquenil /00072602/	S	Oral	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Intravesical	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	Unk	Not Reported
Reactine /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Mg, Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Cutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Pseudoephedrin Hydrochloride	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Not Reported
Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
Xeljanz	S	Unknown	Unk	Not Reported
Certolizumab Pegol	S	Subcutaneous	Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone	S	Oral	25 Mg, Unk	Not Reported
Cortisone	S	Unknown	25 Unk, Unk	Not Reported
Cortisone	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Topical	25 Mg, Unk	Not Reported
Cortisone Acetate	S	Oral	25 Mg, Unk	Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Hydrocortisone Acetate	S	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrocortisone Acetate	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Subcutaneous	Unk	Not Reported
Topicort /00028604/	S	Oral	Unk	Not Reported
Topicort /00028604/	S	Unknown	Unk	Not Reported
Topicort /00028604/	S	Other	Unk	Not Reported
Zyrtec /00884302/	S	Unknown	10 Mg, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Methotrexate	S	Oral	20 Mg, Qd	Not Reported
Methotrexate	S	Oral	1 G, Bid	Not Reported
Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S	Unknown	25 Unk, Unk	Not Reported
Methotrexate	S	Oral	25 Mg, Unk	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Bid	Not Reported
Folic Acid	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Atasol /00020001/	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Lisinopril	C	Unknown	Unk	Not Reported
Salazopyrin	C	Unknown	Unk	Not Reported
Tofacitinib Citrate	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D3	C	Unknown	Unk	Not Reported
Zyrtec-D	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	15957816	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190213604			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Ankylosing Spondylitis; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Inability; Hypermobility Syndrome; Loss Of Personal Independence In Daily Activities; Migraine; Nausea; Rheumatoid Arthritis; Somnolence; Unevaluable Event; Vertigo; Visual Impairment; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Arava			S	Oral			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Celebrex			S	Oral			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported
	Gabapentin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorphone	S	Unknown	Not Reported
Hydromorphone	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Fentanyl	S		Not Reported
Fentanyl	S		Not Reported
Etanercept	S		Not Reported
Lolo	C	Oral	Not Reported
Diclofenac	C		Not Reported
Indomethacin /00003801/	C	Unknown	Not Reported
Acetaminophen W/Codeine Phosphate	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	16739745	EXPEDITED (15-DAY)		OT	DE-ACCORD-152811			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Accord
	Pregabalin			S	Unknown	1 Df, Tid (1 - 1 - 1)		Not Reported
	Sildenafil/Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Ambrisentan			S	Unknown	1 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported
	Eliquis			S	Unknown	1 Df, Bid (1 - 0 - 1) 2.5 Mg Twice Daily		Not Reported
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasmolyt	S	Unknown	Interval: 12 Definition Of The Interval: Hour 1 Df, Qd 1 Number Of Units In The Interval: 1 Definition Of The Interval: Day	Not Reported
Volibris	S	Oral	30 Milligram, Qd	Not Reported
Lyrice	S	Unknown	100 Milligram, Tid	Not Reported
Apixaban	S		2.5 Milligram, Bid	Not Reported
Trospium Chloride	S		30 Mg, Qd Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Omeprazole	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Not Reported
Apixaban	S		2.5 Milligram, Bid	Not Reported
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Ramipril	S	Oral	1 Df, 2x/Day (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour	Accord
Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1) 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd 1 Number Of Units In The Interval: 1	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Definition Of The Interval:
Day

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	16884438	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418381			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Infection; Joint Swelling; Liver Function Test Increased; Off Label Use; Pain; Paralysis; Skin Infection; Treatment Failure; Urinary Tract Infection	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Xeljanz Xr			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Hydroxychloroquine			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17288297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2522989		24 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clear Cell Renal Cell	Rituximab			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Carcinoma; Diarrhoea; Renal Mass; Vomiting	Azathioprine	S	Unknown	Not Reported
	Cyclosporin A	S	Unknown	Not Reported
	Depo-Provera	S	Unknown	Not Reported
	Etanercept	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17620330	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA- 202003002212			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Infection	Hydroxychloroquine			S		400 Mg, Qd		Concordia
	Hydroxychloroquine			S				Concordia
	Aminosalicylic Acid			S		81 Mg, Qd		Not Reported
	Aminosalicylic Acid			S				Not Reported
	Mycophenolate Mofetil			S		1 G, Qd		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Quinacrine			C		100 Mg, Qd		Not Reported
	Quinacrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17682088	EXPEDITED (15-DAY)		OT	DE-ACCORD-179153		45 YR	Female	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate			S	Subcutaneous			Accord
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Oral	Intermittent Usage		Not Reported
	Sulfasalazine			S	Oral	Strength 500 Mg		Not Reported
	Prednisolone			S	Oral	Intermittent Usage Of Low-Dose Prednisolone. Also Received 30 Mg, 7.5 Mg, 5 Mg, 40 Mg, 20 Mg, 10 Mg		Not Reported
	Prednisone			S		Increased To		Not Reported
	Metoprolol			C				Not Reported
	Amlodipine			C				Not Reported
	Prednisone			S				Not Reported
	Prednisolone			S	Oral			Not Reported
Prednisolone			S	Oral	Two Weeks Before Presentation		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17724510	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1948		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error;	Kineret			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Etanercept			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nasopharyngitis; Pain;	Methotrexate	S	Unknown		Not Reported
Peripheral Swelling; Rash;	Naproxen Sodium	S	Unknown		Not Reported
Rheumatoid Arthritis; Skin	Rituxan	S	Intravenous (not		Not Reported
Discolouration; Skin			otherwise specified)		
Disorder; Skin Fissures;	Rituxan	S	Intravenous (not		Not Reported
Smear Cervix Abnormal;			otherwise specified)		
Suicidal Ideation;	Rituxan	S	Intravenous (not		Not Reported
Therapeutic Product Effect			otherwise specified)		
Decreased; Therapeutic	Rituxan	S	Intravenous (not		Not Reported
Response Decreased;			otherwise specified)		
Therapy Non-Responder;	Rituxan	S	Intravenous (not		Not Reported
Tooth Disorder;			otherwise specified)		
Toothache; Weight	Rituxan	S	Intravenous (not		Not Reported
Increased			otherwise specified)		
	Sulfasalazine	S	Unknown		Not Reported
	Naproxen	S	Unknown	1000 Milligram	Not Reported
	Rituximab	S		1000 Milligram	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Plaquenil	S			Not Reported
	Acetaminophen	C	Oral		Not Reported
	Diphenhydramine Hydrochloride	C	Oral		Not Reported
	Ferrous Gluconate	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Methylprednisolone	C	Intravenous (not		Not Reported
			otherwise specified)		
	Naprosyn	C	Unknown		Not Reported
	Oxycontin	C	Unknown		Not Reported
	Oxyneo	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17727246	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP010388		46 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alopecia; Condition	Leflunomide	S	Oral	20 Mg, Qd	Apotex
Aggravated; Drug	Methotrexate	S	Unknown	Unk	Not Reported
Ineffective; Gait	Enbrel	S	Unknown	50 Mg, Q.Wk.	Not Reported
Disturbance; Herpes	Humira	S	Subcutaneous	Unk	Not Reported
Zoster; Musculoskeletal	Plaquenil /00072603/	S	Unknown	Unk	Not Reported
Pain; Musculoskeletal	Sulfasalazine	S	Unknown	Unk	Not Reported
Stiffness; Rheumatoid	Celebrex	C	Unknown	Unk	Not Reported
Arthritis	Tramacet	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	100 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17727437	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010336		50 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Back Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Joint Lock; Joint Swelling; Pain; Polyarthrits; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Therapeutic Product Effect Incomplete	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd (Therapy Duration: 518 Unit Unspecified)		Not Reported
	Arava			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	25 Mg, Q.Wk.		Not Reported
	Xeljanz			C	Oral	5 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17744196	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436856			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Remicade			S	Intravenous (not			Janssen

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Herpes Zoster; Peripheral Swelling; Pneumonia Viral	Enbrel	S	otherwise specified)	Subcutaneous	Not Reported
	Humira	S		Subcutaneous	Not Reported
	Methotrexate	S		Unknown	Not Reported
	Plaquenil	S		Unknown	Not Reported
	Actemra	S		Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17746486	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114212			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Desoximetasone			S	Oral			Sanofi
	Hydroxychloroquine Sulfate			S				Sanofi
	Arava			S	Oral			Sanofi
	Cetirizine Hydrochloride			S				Not Reported
	Folic Acid			S				Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Prednisone			S				Not Reported
	Sulfasalazine			S	Oral	1 G, Bid		Not Reported
	Actemra			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S				Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		400 Mg, Qd		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Not Reported
Tofacitinib Citrate	S		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17761776	EXPEDITED (15-DAY)		DE, HO, OT	FR-ADVANZ PHARMA-202003004184			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Hospitalisation; Off Label Use; Unevaluable Event	Hydroxychloroquine			S	Unknown	Unknown		Concordia
	Hydroxychloroquine			S				Concordia
	Azithromycin			C		Unknown		Not Reported
	Biguanides			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17763474	EXPEDITED (15-DAY)		HO	US-ROCHE-2594510		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Deep Vein Thrombosis; Intentional Product Use Issue; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Remdesivir			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Enoxaparin			C				Not Reported
	Oxygen			C				Not Reported
	Loperamide			C				Not Reported
	Lovenox [Enoxaparin Sodium]			C				Not Reported
	Zosyn			C				Not Reported
	Tylenol			C				Not Reported
	Vancomycin			C				Not Reported
	Zithromax			C				Not Reported
	Calcium Gluconate			C				Not Reported
	Potassium Chloride			C				Not Reported
	Cholecalciferol			C				Not Reported
	Melatonin			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Multivitamin And Mineral			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17767076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2594973		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Neutropenia; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder; Thrombocytopenia	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Advil [Ibuprofen]			C				Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Ketorolac			C	Unknown			Not Reported	
	Leflunomide			C	Unknown			Not Reported	
	Naproxen			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17768317	EXPEDITED (15-DAY)		HO	US-CELLTRION INC.- 2020US022161			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Gastric Disorder; Impaired Work Ability; Infected Lymphocele; Inguinal Hernia; Pneumonitis; Poor Quality Sleep; Prostate Cancer; Psoriasis; Septic Shock; Urticaria	Infliximab (Unknown)			S	Unknown	Unk		Not Reported
	Methotrexate			S				Not Reported
	Remicade			S				Not Reported
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Levofloxacin			S				Not Reported
	Orencia			S				Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S				Not Reported
	Methylprednisolone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17769513	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596273			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis	Doxycycline Hyclate			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17778024	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505945			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Hydroxychloroquine			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
	Tofacitinib Citrate			C	Oral	Extendedrelease		Not Reported	
	Infliximab			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17778044	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505943			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Event; Arthrodesis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Operation; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Leflunomide			S	Oral			Not Reported	
	Cefazolin			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Arava	C	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Viread	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17778065	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505942			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Alopecia; Bronchitis Chronic; Drug Ineffective; Neck Pain; Off Label Use; Spinal Column Injury; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17778124	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505936		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Carpal Tunnel Syndrome; Condition Aggravated; Fatigue;	Remicade			S	Intravenous (not otherwise specified)			Janssen

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Headache; Inflammation; Insomnia; Joint Swelling; Migraine; Musculoskeletal Stiffness; Nasal Congestion; Nasopharyngitis; Pain; Pain In Extremity; Paraesthesia; Rheumatoid Arthritis; Rhinorrhoea; Treatment Failure	Arava Celebrex Enbrel Leflunomide Methotrexate Methotrexate Plaquenil /00072602/ Sulfasalazine Hydroxychloroquine Sulfate Hydroxychloroquine /00072603/ Methotrexate Methotrexate Xeljanz	S S S S S S S S S C C C C	Oral Unknown Unknown Oral Unknown Unknown Oral Rectal Oral Unknown Unknown Unknown Oral	2 Dosage Forms	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17778166	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200505927		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Allergic Oedema; Arthrodesis; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Infection; Joint Surgery; Rash; Rheumatoid Arthritis; Shoulder Arthroplasty; Urticaria	Remicade Apo-Leflunomide Arava Cefazolin Cimzia Enbrel Humira Leflunomide Orencia Plaquenil /00072602/ Rituxan			S S S S S S S S S S S	Intravenous (not otherwise specified) Oral Unknown Unknown Subcutaneous Unknown Subcutaneous Oral Unknown Unknown Intravenous (not			Janssen Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	otherwise specified)	Not Reported
	Naproxen	C	Subcutaneous	Not Reported
	Viread	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
		C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17780182	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505924		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Anaphylactic Shock; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17780260	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505923		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Bone Erosion; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Investigation Abnormal; Joint Swelling; Nausea; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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Arthritis; Therapeutic Product Effect Incomplete; Therapy Non-Responder	Methotrexate	S	Oral	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate Enbrel	S S	Subcutaneous	Not Reported Not Reported
	Plaquenil /00072602/ Xeljanz	S C	Oral	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17780358	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200505849		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Adverse Reaction; Anaphylactic Shock; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Nasopharyngitis; Pain; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17782408	EXPEDITED (15-DAY)		HO, LT	ES-ACCORD-181852		26 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Acute Psychosis; Off Label Use; Suicide Attempt	Hydroxychloroquine	S	Oral	400 Mg Day	Not Reported
	Allopurinol	C	Oral	100 Mg Tablet	Not Reported
	Paracetamol	C	Oral		Not Reported
	Famotidine	C	Oral	20 Mg Tablet	Not Reported
	Doxazosin	C	Oral		Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	2,000 Mg Injection Iv	Not Reported
	Cefixime/Cefixime Trihydrate	C	Oral		Not Reported
	Magnesium Chloride Anhydrous	C	Oral	53 Mg Coated Tablets	Not Reported
	Prednisone	C	Oral		Not Reported
	Carvedilol/Carvedilol Hydrochloride	C	Oral	25 Mg Tablet	Not Reported
	Zemplar	C	Oral	1 Microgram Soft Capsules	Not Reported
	Myfortic	C	Oral	360 Mg Gastro-Resistant Tablets	Not Reported
	Enoxaparin	C	Subcutaneous	20 Mg (2,000 Iu) Injection 0.2 ML	Not Reported
	Fosrenol	C	Oral		Not Reported
	Metamizole Sodium	C	Oral	575 Mg Capsule	Not Reported
	Tacrolimus	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Prednisone	C	Oral		Not Reported
	Tacrolimus	C	Oral		Not Reported
	Tacrolimus	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17791629	EXPEDITED (15-DAY)	DE		ES-ACCORD-181888		84 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Hydroxychloroquine			S	Oral	400 Mg Loading Dose		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	C	Oral	Followed By 200 Mg / Day	Not Reported
Hydroxychloroquine	S	Oral	Loading Dose Of 400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17800794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2187427		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Rituxan			S	Intravenous (not			Not Reported
Blood Cholesterol					otherwise specified)			
Increased; C-Reactive	Rituxan			S	Intravenous (not			Not Reported
Protein Abnormal;					otherwise specified)			
Contraindicated Product	Apo-Azathioprine			S	Unknown			Not Reported
Administered; Drug	Apo-Leflunomide			S	Oral			Not Reported
Hypersensitivity; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Drug	Enbrel			S	Subcutaneous			Not Reported
Intolerance; Off Label Use;	Etanercept			S	Unknown			Not Reported
Rash; Red Blood Cell	Humira			S	Subcutaneous			Not Reported
Sedimentation Rate	Humira			S	Subcutaneous			Not Reported
Abnormal; Synovitis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Parenteral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Tofacitinib	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17807175	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598861		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure	Actemra			S	Unknown			Not Reported	
Fluctuation; Blood	Rituximab			S	Intravenous drip			Not Reported	
Pressure Increased;	Amlodipine Besilate			S	Oral			Not Reported	
Colitis; Dental Caries;	Amlodipine Besilate			S	Oral			Not Reported	
Drug Hypersensitivity;	Asacol			S	Unknown			Not Reported	
Drug Ineffective; Drug	Enbrel			S	Subcutaneous			Not Reported	
Intolerance;	Humira			S	Subcutaneous			Not Reported	
Gastrointestinal Disorder;	Leflunomide			S	Unknown			Not Reported	
Haematochezia;	Methotrexate			S	Subcutaneous			Not Reported	
Hypertension;	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Musculoskeletal Stiffness;	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported	
Nausea; Off Label Use;	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
Off Label Use; Pain In	Simponi			S	Subcutaneous			Not Reported	
Extremity; Peripheral	Xeljanz			S	Unknown			Not Reported	
Swelling; Vitamin D	Acetaminophen			C	Oral			Not Reported	
Deficiency; Weight									
Decreased; Weight									
Increased									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atacand Plus	C	Unknown	Not Reported
Bisoprolol Fumarate	C	Unknown	Not Reported
Depo-Medrol	C		Not Reported
Diamicron	C	Unknown	Not Reported
Diphenhydramine	C	Oral	Not Reported
Ebastine	C		Not Reported
Ferrous Gluconate	C		Not Reported
Folic Acid	C		Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Rosuvastatin Calcium	C		Not Reported
Tylenol	C		Not Reported
Vitamin D3	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17809339	EXPEDITED (15-DAY)	OT		CA-ROCHE-2026232		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hypertension; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Enbrel			S	Unknown	Therapy Duration: 155 Days		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	Therapy Duration: 519 Nos		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valsartan	C	Not Reported
Cortisone	C	Not Reported
Desoximetasone	C	Not Reported
Hydromorphone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17811582	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599879		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Oropharyngeal Pain; Pain; Pulmonary Embolism; Swelling; Upper-Airway Cough Syndrome	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Warfarin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17812560	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS- 050635			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral			Zydus Pharm
	Hidroxiclороquina [Hydroxychloroquine Sulfate]			S	Oral	200 Milligram		Not Reported
	Ceftriaxon			C	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17812589	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020198870		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hyponatraemia; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported	
	Symbicort Turbohaler			S	Respiratory (inhalation)	2 Df, 3x/Day(2-2-2; 2df/8 Hours)		Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported	
	Salbutamol			S	Respiratory (inhalation)	2 Df, 3x/Day(2-2-2 Inh)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17813083	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3408479-00		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome	Kaletra			S	Oral			Not Reported	
	Hidroxicloroquina			S	Unknown			Not Reported	
	Interferon Beta			S	Unknown			Not Reported	
	Azitromicina			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814115	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598381			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Meloxicam	C		Not Reported
Sulfasalazine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601674			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Decreased; Drug Ineffective; Fibromyalgia; Nasal Congestion; Nasopharyngitis; Off Label Use; Serum Ferritin Decreased; Viral Upper Respiratory Tract Infection	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814348	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201711-006311			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Eye Disorder; Fatigue; Pulmonary Mass; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia	
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia	
	Arava			S	Oral	20 Mg, Qd		Not Reported	
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported	
	Methotrexate			S	Oral	175 Mg, Weekly		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Sulfasalazine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814398	EXPEDITED (15-DAY)		HO, OT	BR-ADVANSZ PHARMA-202005005520			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814418	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598071			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Hepatic Cirrhosis; Off Label Use; Synovitis; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814475	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597810			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Intentional Product Use Issue; Off Label Use; Pneumonia	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814493	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597972			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C- Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Human	Humira	S	Subcutaneous	Not Reported
Antichimeric Antibody	Hydroxychloroquine Sulfate	S	Oral	Not Reported
Positive; Juvenile	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Idiopathic Arthritis; Loss Of Personal Independence	Infliximab	S	Unknown	Not Reported
In Daily Activities; Obesity; Off Label Use;	Methotrexate	S	Subcutaneous	Not Reported
Polyarthritis; Psoriasis;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Red Blood Cell Sedimentation Rate	Prednisone	S	Oral	Not Reported
Increased; Septic Shock;	Prednisone	S	Oral	Not Reported
Synovitis; Vomiting	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814506	EXPEDITED (15-DAY)		HO	CA-ROCHE-2597907			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Antibody Test Positive;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthritis; Arthropathy;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Condition Aggravated;	Anakinra			S	Subcutaneous			Not Reported
Diarrhoea; Dizziness;	Enbrel			S	Subcutaneous			Not Reported
Drug Ineffective; Drug Intolerance; Drug Specific	Enbrel			S	Subcutaneous			Not Reported
Antibody; Human	Humira			S	Subcutaneous			Not Reported
Antichimeric Antibody	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Positive; Juvenile	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
Idiopathic Arthritis; Loss Of Personal Independence	Infliximab			S	Unknown			Not Reported
In Daily Activities; Mobility Decreased; Nausea;								
Obesity; Polyarthritis;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use In	Methotrexate	S	Subcutaneous	Not Reported
Unapproved Indication;	Naproxen	S	Unknown	Not Reported
Psoriasis; Red Blood Cell	Orencia	S	Intravenous (not	Not Reported
Sedimentation Rate			otherwise specified)	
Increased; Septic Shock;	Prednisone	S	Oral	Not Reported
Synovitis; Vomiting	Prednisone	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Unknown	Not Reported
	Triamcinolone Hexacetonide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814516	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597952		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition	Actemra			S	Intravenous (not			Not Reported
Aggravated;					otherwise specified)			
Contraindicated Product	Rituximab			S	Intravenous drip			Not Reported
Administered; Cutaneous	Anakinra			S	Subcutaneous			Not Reported
Vasculitis; Drug	Apo-Leflunomide			S	Oral			Not Reported
Ineffective; Drug	Ciclosporin			S	Unknown			Not Reported
Intolerance; Fatigue;	Enbrel			S	Subcutaneous			Not Reported
Mouth Ulceration; Oral	Humira			S	Subcutaneous			Not Reported
Mucosal Exfoliation;	Hydroxychloroquine			S	Oral			Not Reported
Osteoarthritis; Rash; Red	Hydroxychloroquine			S				Not Reported
Blood Cell Sedimentation	Hydroxychloroquine			S	Subcutaneous			Not Reported
Rate Increased;	Hydroxychloroquine			S				Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine			S				Not Reported
Rheumatoid Factor	Hydroxychloroquine			S	Subcutaneous			Not Reported
Positive; Secretion	Hydroxychloroquine			S				Not Reported
Discharge; Spinal	Hydroxychloroquine			S	Unknown			Not Reported
Stenosis; Synovitis;	Hydroxychloroquine			S				Not Reported
Treatment Failure	Hydroxychloroquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Neoral	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814573	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599215		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract;	Actemra			S	Unknown			Not Reported
Diarrhoea; Dizziness;	Gold			S	Unknown			Not Reported
Drug Ineffective; Drug Intolerance; Dry Eye;	Humira			S	Subcutaneous			Not Reported
Fatigue; Feeling Abnormal; Fibromyalgia;	Hydroxychloroquine			S	Unknown			Not Reported
Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Malaise; Mobility Decreased; Muscular Weakness;	Leflunomide			S	Unknown			Not Reported
Musculoskeletal Pain; Musculoskeletal Stiffness;	Meloxicam			S	Unknown			Not Reported
Myalgia; Off Label Use; Pain; Pain In Extremity;	Methotrexate			S	Unknown			Not Reported
Peripheral Swelling; Pulmonary Toxicity; Rash	Mobicox			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Diclofenac			C				Not Reported
	Pantoprazole Magnesium			C				Not Reported
	Plaquenil [Hydroxychloroquine]			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Maculo-Papular; Rash	Sulfate]				
Pruritic; Rheumatoid	Prednisone	C			Not Reported
Arthritis; Rheumatoid	Xeljanz	C	Unknown		Not Reported
Lung; Synovial Cyst;					
Synovitis; Tenosynovitis;					
Treatment Failure; Viral					
Upper Respiratory Tract					
Infection					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599622		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Asthenia; Bone	Actemra			S	Intravenous (not	365.0		Not Reported
Erosion; Contraindicated					otherwise specified)			
Product Administered;	Rituximab			S	Intravenous (not	366.0		Not Reported
Cough; Diarrhoea; Drug					otherwise specified)			
Ineffective; Dyspnoea; Eye	Arava			S	Oral	366.0		Not Reported
Haemorrhage; Gastric	Enbrel			S	Subcutaneous	3.0 Months		Not Reported
Disorder; Gingival	Humira			S	Subcutaneous	3.0 Months		Not Reported
Bleeding; Headache;	Humira			S	Subcutaneous	366.0		Not Reported
Hereditary Angioedema;								
Infection; Liver Function	Hydroxychloroquine			S	Unknown			Not Reported
Test Abnormal; Liver	Hydroxychloroquine			S	Unknown			Not Reported
Function Test Increased;	Hydroxychloroquine			S	Unknown			Not Reported
Nausea; Rash; Syncope;	Methotrexate			S	Unknown	16.0 Years		Not Reported
Urticaria	Orencia			S	Intravenous (not	638.0		Not Reported
					otherwise specified)			
	Plaquenil [Hydroxychloroquine			S	Oral	8.0 Years		Not Reported
	Sulfate]							
	Remicade			S	Intravenous (not			Not Reported
					otherwise specified)			
	Simponi			S	Subcutaneous	396.0		Not Reported
	Xeljanz			C	Oral			Not Reported
	Prednisone			C				Not Reported

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Prevacid			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814607	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599715		73 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Actemra			S	Unknown				Not Reported
Cardiac Failure	Arava			S	Unknown				Not Reported
Congestive; Diverticulitis;	Arava			S	Unknown	Frequency: Cyclical			Not Reported
Drug Ineffective;	Celecoxib			S	Unknown				Not Reported
Dyspnoea; Eye Disorder;	Enbrel			S	Unknown				Not Reported
Lung Disorder; Product	Methotrexate			S	Subcutaneous				Not Reported
Dispensing Error;	Orencia			S	Unknown				Not Reported
Pulmonary Toxicity;	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown				Not Reported
Sensitivity To Weather	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 6.0 Months			Not Reported
Change; Therapeutic	Prednisone			S	Unknown				Not Reported
Product Effect Incomplete	Prednisone			S	Unknown				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Xeljanz			S	Oral				Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C					Not Reported
	Asa			C	Unknown				Not Reported
	Bisoprolol			C	Unknown				Not Reported
	D-Alpha Tocopherol			C	Unknown				Not Reported
	Endocet			C	Unknown				Not Reported
	Folic Acid			C	Unknown				Not Reported
	Indomethacin [Indometacin]			C					Not Reported
	Macrogol			C					Not Reported

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Metoprolol	C	Unknown	Not Reported
Naproxen Sodium	C	Unknown	Not Reported
Pennsaid	C	Topical	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599754			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematous; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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Simponi	S	otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814651	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602457			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814669	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602466		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Joint Swelling; Nausea; Neoplasm Malignant; Off Label Use; Oral Candidiasis; Pain; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased; Thyroid Neoplasm; Toxicity To Various Agents	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Enbrel	S	Subcutaneous	Not Reported
Celebrex	S	Unknown	Not Reported
Celebrex	S		Not Reported
Arava	S	Unknown	Not Reported
Arava	S		Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814676	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597811		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract;	Actemra			S	Unknown			Not Reported
Diarrhoea; Dizziness;	Gold			S	Unknown			Not Reported
Drug Ineffective; Drug Intolerance; Dry Eye;	Humira			S	Subcutaneous			Not Reported
Fatigue; Feeling Abnormal; Fibromyalgia;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Hand Deformity; Joint Range Of Motion	Leflunomide			S	Unknown			Not Reported
Decreased; Joint Swelling;	Methotrexate			S	Unknown			Not Reported
Malaise; Mobility	Mobicox			S	Unknown			Not Reported
Decreased; Muscular Weakness;	Orencia			S	Unknown			Not Reported
Musculoskeletal Pain;	Depo-Medrol			C	Intra-articular			Not Reported
Musculoskeletal Stiffness;	Diclofenac			C	Unknown			Not Reported
Myalgia; Off Label Use;	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
Pain; Pain In Extremity;	Pantoprazole Magnesium			C	Unknown			Not Reported
Peripheral Swelling;	Xeljanz			C	Oral			Not Reported
Pulmonary Toxicity; Rash								
Maculo-Papular; Rash								
Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory								

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Detailed Report

Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814706	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600418			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814711	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA131305		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Diverticulitis; Drug Ineffective; Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Pain; Pulmonary Embolism; Pulmonary Thrombosis; Renal Failure; Sepsis; Stent Placement; Terminal State; Thrombosis	Hydroxychloroquine			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S		Unk		Sanofi
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Anakinra			S		Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Gold			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not	Unk		Not Reported

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Remicade	S	otherwise specified)	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituximab	C		Unk	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		Unk	Not Reported
Ilaris	C	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814822	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600568			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported
Arthralgia; Blood	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Creatinine Increased;	Humira			S	Subcutaneous			Not Reported
Drug Hypersensitivity;	Ciclosporin			S	Unknown			Not Reported
Drug Ineffective; Drug	Ciclosporin			S	Unknown			Not Reported
Intolerance; Loss Of	Enbrel			S	Unknown			Not Reported
Personal Independence In	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Daily Activities; Mobility	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Decreased;	Methotrexate			S	Unknown			Not Reported
Musculoskeletal Pain;	Orencia			S	Unknown	Therapy Duration: 7.0 Months		Not Reported
Neck Pain; Off Label Use;	Sulfasalazine			S	Unknown			Not Reported
Pain In Extremity; Pain In	Xeljanz			S	Oral			Not Reported
Jaw; Rheumatoid Arthritis	Gabapentin			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814831	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598090			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Burning Sensation; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Nausea; Oral Discomfort; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			C	Oral			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814839	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598481		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort;	Actemra	S	Unknown		Not Reported
Arthropathy; Diarrhoea;	Arava	S	Oral		Not Reported
Drug Hypersensitivity;	Arava	S	Unknown		Not Reported
Drug Ineffective;	Cimzia	S	Subcutaneous	Solution Subcutaneous	Not Reported
Erythema; Impaired Work	Enbrel	S	Unknown		Not Reported
Ability; Musculoskeletal	Humira	S	Subcutaneous		Not Reported
Disorder; Off Label Use;	Orencia	S	Unknown		Not Reported
Skin Warm	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Methotrexate	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814864	EXPEDITED (15-DAY)	LT		ES-TEVA-2020-ES-1239014		60 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intrusive Thoughts;	Hidroxyclozoquina (2143a)			S	Oral	200mg Every 12 Hours		Teva
Suicide Attempt	Levofloxacin (2791a)			C	Unknown			Not Reported
	Cortic - Corticoide			C	Intravenous bolus	Bolus Corticosteroids Iv		Not Reported
	Septrin			C	Unknown			Not Reported
	Kaletra			C	Oral			Not Reported
	Acetilcisteina (233a)			C	Unknown			Not Reported
	Ciclosporina (406a)			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814963	EXPEDITED (15-DAY)	OT		CA-ROCHE-2601285		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug	Rituxan			S	Intravenous (not			Not Reported
Ineffective; Drug					otherwise specified)			
Intolerance; Nausea; Off	Rituximab			S	Unknown			Not Reported
Label Use; Pain;								
Rheumatoid Arthritis;								

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Stomatitis; Swelling	Doxycycline	S	Unknown	Not Reported
	Doxycycline	S	Unknown	Not Reported
	Doxycycline Hyclate	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814968	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600417			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stomatitis; Swelling	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

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Leflunomide	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17814994	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832711		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Neoral			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815016	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131570			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

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Drug Ineffective; Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S		2 Df, Qd (Dose: 200 Mg)	Sanofi
	Methotrexate	S	Unknown	1 Df, Qw	Not Reported
	Methotrexate	S	Unknown	1 Df, Qw	Not Reported
	Leflunomide	S		1 Df, Qd	Sanofi
	Orencia	S			Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Humira	S	Subcutaneous	40 Mg	Not Reported
	Enbrel	S		1 Df, Qw	Not Reported
	Actemra	S			Not Reported
	Xeljanz	C			Not Reported
	Sulfasalazine	C			Not Reported
	Wellbutrin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815025	EXPEDITED (15-DAY)		OT	NVSC2020GB043308		50 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dermatomyositis; Disease Progression; Product Use In Unapproved Indication; Pseudomonas Infection; Pulmonary Fibrosis; Skin Ulcer; Treatment Failure	Rituximab			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Novartis
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	60 Mg		Not Reported
	Prednisolone			S				Not Reported
	Dapsone			S	Unknown	Unk		Not Reported
	Mycophenolate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815046	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602428		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Pain;	Rituximab	S	Unknown	Not Reported
Diarrhoea; Dizziness;	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Drug Ineffective; Drug Intolerance; Fibromyalgia; Intentional Product Use	Celebrex	S	Unknown	Not Reported
Issue; Nausea; Oedema; Off Label Use;	Celebrex	S	Unknown	Not Reported
Rheumatoid Arthritis;	Enbrel	S	Subcutaneous	Not Reported
Synovitis; Underdose; Vomiting	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815068	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0123276			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Arthritis	Atorvastatin			S	Oral			Not Reported	
	Methotrexate			S				Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Alprazolam			C	Oral			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Naprosyn			C				Not Reported	
	Pantoloc			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815160	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602524		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Pressure Increased;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Dermatomyositis;	Rituximab			S				Not Reported	
Diarrhoea; Drug Ineffective; Foot Fracture;	Methotrexate			S	Unknown			Not Reported	
Infusion Related Reaction;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Migraine; Off Label Use;	Acetaminophen			C	Unknown			Not Reported	
Pain In Extremity; Poor Venous Access; Post-Traumatic Neck Syndrome; Rhinorrhoea;	Diflucan			C				Not Reported	
Road Traffic Accident;	Diphenhydramine Hydrochloride			C	Oral			Not Reported	
Thrombophlebitis	Euro D			C				Not Reported	
	Leucovorin [Folinic Acid]			C				Not Reported	
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			C				Not Reported	
	Risedronate Sodium			C				Not Reported	
	Sulfamethoxazole;Trimipramine			C				Not Reported	
	Zopiclone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815187	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598423		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthrodesis;	Actemra			S	Unknown			Not Reported	
Drug Ineffective; Joint Swelling; Knee	Anakinra			S	Subcutaneous			Not Reported	
Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Anakinra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Infliximab			S	Intravenous (not			Not Reported	

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		otherwise specified)	
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tocilizumab	S	Unknown	Not Reported
Desoximetasone	C		Not Reported
Methotrexate	C		Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815201	EXPEDITED (15-DAY)		OT	CA-SA-2020SA114144		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Desoximetasone			S	Oral			Sanofi
Alopecia; Arthralgia; Blood	Hydroxychloroquine			S				Sanofi
Cholesterol Increased;	Hydroxychloroquine Sulfate			S				Sanofi
Contraindicated Product	Plaquenil			S		400 Mg, Qd		Sanofi
Administered; Drug	Arava			S				Sanofi
Ineffective; General	Diclofenac Sodium			S		Unk		Not Reported
Physical Health	Prednisone			S				Not Reported
Deterioration; Headache;	Prednisone			S		Unk		Not Reported
Hypersensitivity;	Folic Acid			S		5 Mg, Qd		Not Reported
Hypertension; Joint	Methotrexate			S		20 Mg, Qw		Not Reported
Swelling; Maternal	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
Exposure During	Methotrexate			S	Oral	25 Mg		Not Reported
Pregnancy;	Sulfasalazine			S				Not Reported
Musculoskeletal Stiffness;	Sulfasalazine			S	Oral			Not Reported
Pain; Pemphigus;	Pseudoephedrine Hydrochloride			S				Sanofi
Pericarditis; Product Use	Alendronate Sodium			S				Not Reported
Issue; Rheumatic Fever;	Cortisone Acetate			S				Not Reported
Rheumatoid Arthritis;								
Swelling; Swollen Joint								
Count Increased;								
Synovitis; Systemic Lupus								

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Erythematous;	Cetirizine Hydrochloride	S				Not Reported
Therapeutic Product Effect	Actemra	S				Not Reported
Decreased; Treatment	Cimzia	S				Not Reported
Failure; Type 2 Diabetes	Cimzia	S				Not Reported
Mellitus	Enbrel	S	Subcutaneous			Not Reported
	Humira	S	Subcutaneous	40 Mg, Qd		Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan	S				Not Reported
	Simponi	S	Subcutaneous			Not Reported
	Sulfathalidine	S				Not Reported
	Xeljanz	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815212	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2020-014626			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Prednisolone			S	Unknown			Bausch And Lomb
Ageusia; Arthralgia;	Glyceryl Trinitrate			S	Unknown			Not Reported
Depression; Dna Antibody	Aspirin			S	Unknown			Not Reported
Negative; Drug Interaction;	Colecalciferol			S	Unknown			Not Reported
Fibromyalgia; Gait	Ezetimibe			S	Unknown			Not Reported
Disturbance; Liver	Ivabradine			S	Unknown			Not Reported
Function Test Abnormal;	Leflunomide			S	Unknown			Not Reported
Migraine; Nausea; Panic	Methotrexate			S	Unknown			Not Reported
Attack; Paraesthesia;	Mycophenolate Mofetil			S	Unknown			Not Reported
Psoriasis; Psoriatic	Paracetamol			S	Unknown			Not Reported
Arthropathy; Respiratory	Prasugrel			S	Unknown			Not Reported
Syncytial Virus Infection;	Ramipril			S	Unknown			Not Reported
Sleep Disorder; Suicidal								
Ideation; Systemic Lupus								
Erythematous;								
Tachyarrhythmia; Type 1								
Diabetes Mellitus; Urinary								
Tract Infection; Viral								

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Tonsillitis	Reboxetine	S	Unknown	Not Reported
	Sildenafil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topiramate	S	Unknown	Not Reported
	Endone	S	Unknown	Not Reported
	Glucagen	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Mirena	S	Unknown	Not Reported
	Novorapid	S	Unknown	Not Reported
	Oxycontin	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599760		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported
Adverse Drug Reaction;	Rituximab			S	Intravenous drip			Not Reported
Alanine Aminotransferase	Apo-Hydroxyquine			S	Unknown			Not Reported
Increased; Alopecia;	Enbrel			S	Subcutaneous			Not Reported
Anxiety; Arthralgia;	Humira			S	Subcutaneous			Not Reported
Aspartate	Humira			S	Subcutaneous			Not Reported
Aminotransferase	Humira			S	Subcutaneous			Not Reported
Increased; Asthenia;	Hydroxychloroquine			S	Unknown			Not Reported
Depression; Diarrhoea;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Drug Dependence; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Ineffective; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Intolerance; Drug Use	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Disorder; Fall; Fatigue;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Headache; Inflammation;	Infliximab			S	Unknown			Not Reported
Joint Injury; Liver Disorder;	Methotrexate			S	Unknown	9.0 Years		Not Reported
Malaise; Nausea; Off								
Label Use; Pain; Red								
Blood Cell Sedimentation								

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Rate Increased; Rheumatoid Arthritis; Synovitis; Treatment Failure	Methotrexate	S	Unknown	9.0 Years	Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	3.0 Months	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	12.0 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	2.0 Months	Not Reported
	Xeljanz	S	Oral	2.0 Months	Not Reported
	Xeljanz	S	Unknown		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Acetaminophen	C	Unknown		Not Reported
	Cetirizine Hydrochloride	C	Unknown		Not Reported
	Cortisone	C	Unknown		Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C	Unknown		Not Reported
	Gabapentin	C	Unknown		Not Reported
	Paracetamol	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown		Not Reported

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22-May-2020	17815260	EXPEDITED (15-DAY)		DS, OT	CA-SAKK- 2020SA115119AA		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Adverse Event; Alopecia;	Desoximetasone	S			Sanofi
Anti-Cyclic Citrullinated	Desoximetasone	S			Sanofi
Peptide Antibody Positive;	Desoximetasone	S	Oral	Unk	Sanofi
Arthropathy; Condition	Cortisone Acetate	S	Oral		Not Reported
Aggravated; Discomfort;	Cortisone Acetate	S	Oral		Not Reported
Drug Ineffective; Drug	Diclofenac Sodium	S			Not Reported
Intolerance; Duodenal	Topicort	S	Subcutaneous		Sanofi
Ulcer Perforation; Fatigue;	Topicort	S			Sanofi
Glossodynia; Hand	Topicort	S	Oral	Unk	Sanofi
Deformity; Hepatic	Prednisone	S			Not Reported
Enzyme Increased;	Arava	S	Oral	20 Mg	Sanofi
Hypersensitivity; Infusion	Arava	S	Oral	Unk	Sanofi
Related Reaction;	Cetirizine Hydrochloride	S		10 Mg	Not Reported
Intentional Product Use	Cetirizine Hydrochloride	S		20 Mg	Not Reported
Issue; Joint Swelling; Live	Cetirizine Hydrochloride	S			Not Reported
Birth; Maternal Exposure	Folic Acid	S	Oral	1 Mg	Not Reported
During Pregnancy; Off	Folic Acid	S	Oral	5 Unk	Not Reported
Label Use; Pain;	Folic Acid	S		1 Unk	Not Reported
Pemphigus; Pericarditis;	Folic Acid	S		5 Unk	Not Reported
Rash; Rheumatoid	Alendronate Sodium	S	Oral		Not Reported
Arthritis; Rheumatoid	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
Factor Positive; Swelling;	Hydroxychloroquine	S		400 Unk	Sanofi
Synovitis; Systemic Lupus	Hydroxychloroquine	S		Unk	Sanofi
Erythematosis; Treatment	Hydroxychloroquine Sulfate	S		400 Mg, Qd	Sanofi
Failure; Wound	Hydroxychloroquine Sulfate	S	Oral	40 Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Oral	Unk	Sanofi
	Hydroxychloroquine Sulfate	S	Subcutaneous	400 Mg, Qd	Sanofi
	Methotrexate	S	Oral	25 Mg	Not Reported
	Methotrexate	S	Oral	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	Unk	Not Reported
	Methotrexate	S		Unk	Not Reported

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Methotrexate	S	Oral	25 Mg, Qd	Not Reported
Methotrexate	S	Intra-arterial	25 Unk	Not Reported
Paracetamol	S			Not Reported
Plaquenil	S		400 Mg, Qd	Sanofi
Plaquenil	S		40 Unk	Sanofi
Plaquenil	S	Oral	40 Unk	Sanofi
Prednisone	S			Not Reported
Prednisone	S			Not Reported
Sarilumab	S			Sanofi
Sulfasalazine	S	Oral	1 G, Qd	Not Reported
Sulfasalazine	S	Oral	500 Mg	Not Reported
Leflunomide	S	Oral		Sanofi
Leflunomide	S	Oral		Sanofi
Pseudoephedrine Hydrochloride	S			Sanofi
Pseudoephedrine Hydrochloride	S		25 Mg	Sanofi
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported
Methotrexate Sodium	S	Subcutaneous		Not Reported
Methotrexate Sodium	S	Oral	25 Mg	Not Reported
Cetirizine Hydrochloride And Pseudoephedrine Hydrochloride	S			Not Reported
Cimzia	S	Subcutaneous		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	Unk	Not Reported
Humira	S	Subcutaneous	4 Mg	Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Subcutaneous		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Subcutaneous	Unk	Not Reported

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Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S			Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Unk	Not Reported
Stelara	S			Not Reported
Sulfathalidine	S			Not Reported
Sulfathalidine	S	Subcutaneous	Unk	Not Reported
Tofacitinib Citrate	S	Subcutaneous		Not Reported
Tofacitinib Citrate	S		Unk	Not Reported
Xeljanz	S			Not Reported
Cortisone Acetate	S	Topical	25 Mg	Not Reported
Acetaminophen	S			Not Reported
Reactine [Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride]	S		10 Mg	Not Reported
Reactine [Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride]	S		20 Unk	Not Reported
Atasol [Paracetamol]	C			Not Reported
Salazopyrin	C			Not Reported
Tofacitinib Citrate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815323	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602209		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Hepatic	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Apo-Prednisone			S	Oral			Not Reported	
	Arava			S	Unknown			Not Reported	

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Enzyme Increased;	Enbrel	S	Subcutaneous	Not Reported
Injection Site Reaction;	Gold	S	Unknown	Not Reported
Joint Swelling; Loss Of	Humira	S	Subcutaneous	Not Reported
Personal Independence In	Leflunomide	S	Unknown	Not Reported
Daily Activities;	Methotrexate	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Nail Disorder; Off Label	Prednisone	S	Oral	Not Reported
Use; Onychomycosis;	Prednisone	S	Oral	Not Reported
Rheumatoid Arthritis;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Treatment Failure	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815461	EXPEDITED (15-DAY)		DE, OT	CA-ROCHE-2600163		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Bone	Actemra			S	Unknown			Not Reported
Erosion; C-Reactive	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Protein Abnormal; C-	Rituxan			S	Unknown			Not Reported
Reactive Protein	Sulfasalazine			S	Unknown			Not Reported
Increased; Deep Vein								
Thrombosis; Diverticulitis;								
Drug Ineffective;								

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Intentional Product Use	Sulfasalazine	S	Unknown	Not Reported
Issue; Intestinal Sepsis;	Methotrexate	S	Unknown	Not Reported
Joint Swelling; Myocardial	Leflunomide	S	Unknown	Not Reported
Infarction; Off Label Use;	Enbrel	S	Unknown	Not Reported
Osteoarthritis; Pain;	Humira	S	Subcutaneous	Not Reported
Pulmonary Embolism;	Humira	S	Unknown	Not Reported
Pulmonary Thrombosis;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Red Blood Cell	Remicade	S	Unknown	Not Reported
Sedimentation Rate	Remicade	S	Unknown	Not Reported
Increased; Renal Failure;	Doxycycline	S	Unknown	Not Reported
Rheumatoid Arthritis;	Orencia	S	Unknown	Not Reported
Rheumatoid Factor	Sodium Aurothiomalate	S	Unknown	Not Reported
Positive; Sepsis; Synovitis;	Simponi	C		Not Reported
Terminal State;	Xeljanz	C		Not Reported
Thrombosis				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815481	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237783		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Azathioprine			S	Unknown			Not Reported	
Osteoporotic Fracture;	Methotrexate			S	Subcutaneous			Barr	
Spinal Compression	Actemra			S	Subcutaneous			Not Reported	
Fracture	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Acetaminophen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815499	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600237			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Gold	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815502	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600347			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Alopecia	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			C	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815592	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597636			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort;	Actemra	S	Unknown	Not Reported
Alopecia; Arthralgia;	Rituximab	S	Intravenous drip	Not Reported
Diarrhoea; Drug	Apo-Leflunomide	S	Unknown	Not Reported
Ineffective; Joint Stiffness;	Celebrex	S	Unknown	Not Reported
Liver Function Test	Enbrel	S	Unknown	Not Reported
Abnormal; Mobility	Leflunomide	S	Unknown	Not Reported
Decreased; Off Label Use;	Methotrexate	S	Unknown	Not Reported
Pneumonia; Swelling;	Orencia	S	Unknown	Not Reported
Therapeutic Product Effect	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Decreased; Treatment	Sulfasalazine	S	Unknown	Not Reported
Failure; Vomiting	Bifidobacterium Bifidum	C	Unknown	Not Reported
	Loperamide	C	Oral	Not Reported
	Pantoprazole	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815625	EXPEDITED (15-DAY)		DE	MX-ADVANZ PHARMA-202005005423			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S		200 Mg, Bid(Q12h)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Ceftriaxone Sodium			C				Not Reported
	Clarithromycin			C				Not Reported
	Oseltamivir Phosphate			C				Not Reported
	Methylprednisolone			C				Not Reported
	Norepinephrine			C				Not Reported
	Meropenem			C				Not Reported
	Enoxaparin			C				Not Reported

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22-May-2020	17815637	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597966			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815690	DIRECT	Y	LT			93 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Therapy Cessation	Hydroxychloroquine Sulfate			S	Oral			Sandoz
	Acetaminophen 650 Mg			C				Not Reported
	Albuterol Mdi			C				Not Reported
	Aspirin 81mg			C				Not Reported
	Atorvastatin 10mg			C				Not Reported
	Benzonatate 100 Mg			C				Not Reported
	Finasteride 5mg			C				Not Reported
	Guaifenesin -La 600mg			C				Not Reported
	Heparin 5000 Units			C				Not Reported
	Hydrocodone/Homatropine Syrup			C				Not Reported
	Metoprolol Succinate 100 Mg			C				Not Reported
	Morphine 1 Mg Ivp			C				Not Reported

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Tamsulosin 0.4mg
Piperacillin/Tazobactam 3.375
Gm Ivpb

C
C

Not Reported
Not Reported

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22-May-2020	17815692	EXPEDITED (15-DAY)		OT	CA-ROCHE-2184306			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rash	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Citalopram Hydrobromide			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Mirtazapine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815728	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600346			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Xeljanz	C		Not Reported
	Simponi	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815756	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0739		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Contraindicated Product Administered; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Kineret			S				Not Reported
	Actemra			S				Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Desoximetasone			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815825	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598500		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Protein Abnormal; Contusion; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Joint Swelling; Laboratory Test Abnormal; Liver Function Test Increased; Musculoskeletal Stiffness; Off Label Use; Pain; Rheumatoid Arthritis; Treatment Failure; White Blood Cell Count Decreased	Apo-Leflunomide Arava Enbrel Hydroxychloroquine Sulfate Leflunomide Methotrexate Methotrexate Orencia Phthalylsulfathiazole Plaquenil [Hydroxychloroquine Sulfate] Simponi Sulfasalazine Prednisone Prednisone Xeljanz	S S S S S S S S S S S S S C C C	Oral Oral Unknown Oral Unknown Oral Unknown Unknown Unknown Oral Subcutaneous Unknown Oral Oral Unknown	10 Mg 1 Every 1 Weeks 1 Every 1 Days	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815846	EXPEDITED (15-DAY)		OT	CA-ROCHE-2597354			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815847	NON-EXPEDITED			NVSC2020US140199			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Hydroxychloroquine Sulfate Tablets Usp			S	Unknown	200 Mg, Unknown		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815890	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2597924			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting; Wheelchair User	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Apo-Naproxen			S	Unknown			Not Reported	
	Apo-Prednisone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gammagard			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Naproxen			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Prednisone			S	Oral			Not Reported	

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	Sulfasalazine	S	Oral	Not Reported
	Triamcinolone	S	Subcutaneous	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Not Reported
	Triamcinolone Acetonide	S		Not Reported
	Triamcinolone Acetonide	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815918	EXPEDITED (15-DAY)	OT		CA-ROCHE-2600989		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii;	Methotrexate			S	Subcutaneous			Not Reported
Depression; Diarrhoea;	Rituximab			S	Unknown			Not Reported
Drug Ineffective; Gait	Arava			S	Unknown			Not Reported
Disturbance; Gait Inability;	Enbrel			S	Unknown			Not Reported
Joint Range Of Motion	Gold			S	Unknown			Not Reported
Decreased; Memory	Humira			S	Subcutaneous			Not Reported
Impairment;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Musculoskeletal Disorder;	Orencia			S	Unknown			Not Reported
Off Label Use;	Simponi			S	Subcutaneous			Not Reported
Rheumatoid Arthritis;	Sodium Aurothiomalate			S	Unknown			Not Reported
Sleep Disorder; Treatment	Sulfasalazine			S	Unknown			Not Reported
Noncompliance								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815953	EXPEDITED (15-DAY)	OT		CA-ROCHE-2600622		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthritis; Drug	Rituximab			S	Intravenous (not			Not Reported
Ineffective; Drug					otherwise specified)			
Intolerance; Drug	Apo-Leflunomide			S	Unknown			Not Reported
Tolerance Decreased;	Enbrel			S	Unknown			Not Reported
Lymphoma; Neoplasm								
Malignant; Off Label Use;								

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Onychoclasia; Synovitis; Tooth Loss	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Zostavax	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17815968	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599481		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Benign Neoplasm; Bladder Operation; Disability; Drug Ineffective; Fatigue; Headache; Influenza Like Illness; Malaise; Off Label Use; Peripheral Swelling; Spinal Pain; Urinary Tract Infection; Vaginal Haematoma	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	6.0 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral	105.0 Days		Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Ergocalciferol			C	Oral			Not Reported

FDA Adverse Event Reporting System

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Humira	C	Subcutaneous	Not Reported
Leflunomide	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816129	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602954		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Nasopharyngitis; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous drip			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Arava			C	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816143	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR- 1238595		61 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged	Amoxicilline Trihydratee	S	Oral	Teva
	Clavulanique (Acide)	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816150	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603071		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Incorrect Route Of Product Administration; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Kevzara			S				Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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Tofacitinib Citrate	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Rabeprazole Sodium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816368	EXPEDITED (15-DAY)		DS	CA-ROCHE-2600951		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Depression; Diarrhoea; Disability; Drug Ineffective; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816376	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598424		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin;	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

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Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816378	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1237799		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Azathioprine			S	Unknown			Not Reported	
Amnesia; Drug Ineffective;	Mycophenolate Mofetil			S	Unknown			Teva	
Fatigue; Gastric Ulcer;	Methotrexate			S	Unknown			Barr	
Hallucination; Malaise;	Plaquenil			S	Unknown			Not Reported	
Oesophageal Disorder;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Throat Cancer;									
Thrombosis	Sulfasalazine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tacrolimus	S	Unknown	6 Dosage Forms Daily;	Not Reported
Tacrolimus	S	Unknown	5 Dosage Forms Daily;	Not Reported
Prednisone	C	Oral	17 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816424	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238080			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Methotrexate			S	Subcutaneous			Barr
	Minocycline Hydrochloride			S	Unknown			Actavis
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported
	Leflunomide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816425	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238156		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Neoplasm	Azathioprine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Minocycline	S	Unknown	Actavis
	Methotrexate	S	Subcutaneous	Barr
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816433	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600223		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Endocervical			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Prednisone			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816694	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601297		77 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abscess; Arthritis Bacterial; Bladder Transitional Cell Carcinoma; Drug Ineffective; Nausea; Synovitis; Tachycardia; Type 2 Diabetes Mellitus	Rituximab			S	Unknown			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Desoximetasone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816728	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2020202244		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Off Label Use; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Inhixa			C	Subcutaneous	40 Mg		Not Reported	
	Sirtap			C	Intravenous (not otherwise specified)	2 G		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816729	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020200441		71 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Tazocilline			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816748	EXPEDITED (15-DAY)		OT	NVSC2020GB054189		29 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Infarction; Cerebrovascular Accident; Drug Ineffective; Transient Ischaemic Attack; Treatment Failure	Hydroxychloroquine			S	Unknown	Unk		Novartis	
	Hydroxychloroquine			S				Novartis	
	Hydroxychloroquine			S				Novartis	
	Clopidogrel			S	Unknown	Unk		Not Reported	
	Apixaban			S	Unknown	Unk		Not Reported	
	Rivaroxaban			S	Unknown	Unk		Not Reported	
	Warfarin			S	Unknown	Unk		Not Reported	
	Warfarin			S				Not Reported	
	Atorvastatin			S	Unknown	High Dose		Not Reported	
	Atorvastatin			S				Not Reported	
Atorvastatin			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816759	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601313			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

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	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816805	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020202843		55 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Atorvastatin Calcium			S	Unknown	10.0 Mg, 1x/Day		Pfizer
Arthralgia; Arthritis; Blood Glucose Abnormal;	Bisoprolol			S	Unknown	2.5 Mg, 2x/Day		Not Reported
Cataract; Dizziness; Ear Discomfort; Erythema; Fatigue; Headache;	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg		Not Reported
Hypotension;	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
Inappropriate Schedule Of Product Administration;	Sandostatin			S	Intramuscular	20 Mg 4 Every 1 Week		Not Reported
Joint Stiffness; Muscle Spasms; Nausea;	Sandostatin			S	Subcutaneous	50 Ug Total		Not Reported
Rheumatoid Arthritis; Vomiting	Sandostatin			S	Intramuscular	30 Mg, Monthly		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5.0 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816921	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1238603		26 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aortic Valve Incompetence; Asthenia;	Azathioprine			S	Unknown			Not Reported
Chest Discomfort; Drug Ineffective; Dyspnoea;	Mycophenolate Mofetil			S	Oral	2000 Milligram Daily;		Teva
Headache; Heart Rate Increased; Hyperhidrosis;	Hydroxychloroquine Sulfate			S	Unknown	300 Milligram Daily;		Not Reported
Left Ventricular Dilatation; Myocarditis; Nausea;	Acetylsalicylic Acid			C	Unknown	81 Milligram Daily;		Not Reported
	Colchicine			C	Unknown	.6 Milligram Daily;		Not Reported

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Nephritis; Pleuritic Pain;	Naproxen	C	Unknown	500 Milligram Daily;	Not Reported
Systemic Lupus	Prednisone	C	Unknown	50 Milligram Daily;	Not Reported
Erythematosis; Treatment					
Failure; Vasculitis					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816922	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238103		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown	2.8571 Milligram Daily; 40 Mg, 1 Every 2 Weeks		Barr
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816944	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600620			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Medication Error; Musculoskeletal Disorder; Off Label Use; Synovitis;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

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Therapeutic Product Effect Decreased; Treatment Failure; X-Ray Abnormal	Azathioprine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816994	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2020M1047833		56 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Off Label Use	Azithromycin			S	Oral	500 Mg Dia		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan
	Hydroxicloroquina /00072601/			S				Mylan
	Hydroxicloroquina /00072601/			S				Mylan
	Anakinra			S	Subcutaneous	100 Milligram		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg Dia		Mylan
	Tocilizumab			S				Mylan
	Tocilizumab			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817025	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA128122		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Cell Carcinoma; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypersensitivity;	Leflunomide			S	Unknown	Unk		Sanofi
	Codeine			S	Unknown	Unk		Not Reported
	Alendronate Sodium			S	Unknown	70 Mg, 1 Every 1 Week		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Methotrexate			S	Unknown	12 Mg, 1 Every 1 Week		Not Reported

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Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Methotrexate	S	Unknown	12 Mg	Not Reported
Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Skin Necrosis; Skin Ulcer	Methotrexate	S	Unknown	12.5 Mg	Not Reported
	Methotrexate	S	Unknown	12.5 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, 1 Every 1 Week	Not Reported
	Methotrexate	S	Unknown	10 Mg, 1 Every 1 Week	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, 1 Every 1 Week	Not Reported
	Humira	S	Subcutaneous	40 Mg, 1 Every 2 Weeks	Not Reported
	Orencia	S	Unknown	780 Mg, 1 Every 1 Week	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, 2 Every 1 Day	Not Reported
	Actemra	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
	Actemra	S	Unknown	360 Mg, 1 Every 1 Month	Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Prednisone	C			Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817030	EXPEDITED (15-DAY)			US-ADVANS PHARMA- 202004004686			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pharyngitis; Sinus Disorder	Hydroxychloroquine			S	Unknown	200 Mg		Concordia	
	Xeljanz			S	Oral	5 Mg, Bid (5mg 1 Tablet By Mouth Twice A Day)		Not Reported	
	Xeljanz			S				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817236	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505926		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Synovitis; Throat Tightness	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Supeudol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817261	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603030		83 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Contraindicated Product Administered	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Gabapentin			S	Oral			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Fentanyl			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Oxycontin			S	Unknown	Extended Release		Not Reported	

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Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Nasonex	C	Unknown	Metered Dose Not Reported
Oxycodone Terephthalate	C		Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Risedronate Sodium	C	Unknown	Not Reported
Trazodone Hydrochloride	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605594			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817283	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1050069		81 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Vomiting	Lopinavir/Ritonavir			S	Oral	1 Dosage Form, Bid		Not Reported	
	Naloxone/Oxycodone			S	Oral	10 Milligram, Bid		Not Reported	
	Hidroxicloroquina /00072601/			S	Oral	Unk		Mylan	
	Prolia			C	Subcutaneous	Unk		Mylan	
	Stilnox			C	Oral	10 Milligram, Qd		Mylan	
	Pantoprazol /01263201/			C	Oral	20 Milligram, Qd		Mylan	
	Calcium Carbonate W/Colecalciferol			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817285	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237763			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported	
	Leflunomide			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817287	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237764			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Enbrel			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Amoxicillin Trihydrate;Clavulanate Potassium			C	Unknown			Not Reported	
	Amoxil [Amoxicillin]			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817367	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1051084		77 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Plaquenil /00072603/			S	Oral	400 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817430	EXPEDITED (15-DAY)		DE	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051273			Unknown	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy	Azithromycin			S	Oral	500 Milligram		Zyodus Pharm	
	Hydroxychloroquine			S	Oral	400 Milligram		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	20 Milligram		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Milligram		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab			S				Not Reported	
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram Every 8 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817482	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601342		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Rituximab;Vorhyaluronidase Alfa			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enbrel	S	Subcutaneous	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Amitriptyline	C	Unknown	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Imitrex [Sumatriptan]	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817551	EXPEDITED (15-DAY)	DS, OT		CA-TEVA-2020-CA-1238086		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Exposure During Pregnancy; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Aamitriptyline			C	Unknown	10 Milligram Daily;		Not Reported
	Azithromycin			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Esomeprazole Sodium			C	Unknown			Not Reported
	Gabapentin			C	Unknown	400 Milligram Daily;		Not Reported
	Metonia			C	Unknown			Not Reported
	Prednisone			C	Unknown	8 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ranitidine	C	Unknown					Not Reported	
	Xeljanz	C	Oral		5 Milligram Daily;			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817558	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238074		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817621	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238124			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817630	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201711-006337			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Hydroxychloroquine			S	Oral	400 Mg, Freq: Unk X 1 Days		Concordia
	Leflunomide			S	Oral	20 Mg, Unk		Not Reported
	Sodium Aurothiomalate			S	Parenteral	50 Mg, Unk		Not Reported
	Actemra			S	Unknown	8 Mg, Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	20 Mg, Qd		Not Reported
	Orencia			S	Unknown	750 Mg, Unk		Not Reported
	Apo Lefunomide			S	Unknown	20 Mg, Freq: Unk X 1 Days		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meloxicam			C		Unk		Not Reported
	Sulfasalazine			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817647	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238602		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported	
	Amoxicillin Sodium;Clavulanate Potassium			C	Unknown			Not Reported	
	Amoxil [Amoxicillin]			C	Unknown			Not Reported	
	Bacillus Calmetteguerin Bcg			C	Unknown			Not Reported	
	Bacillus Calmetteguerin Bcg			C	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817829	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238072		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Parenteral			Barr
	Methotrexate			S	Subcutaneous			Barr
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817869	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238148			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Headache; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Stomatitis; Tinnitus; Treatment Failure	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Simponi	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817873	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238139			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Azathioprine			S	Oral	200 Milligram Daily;		Not Reported
	Leucovorin Calcium			S	Unknown			Barr
	Methotrexate			S	Subcutaneous			Barr
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	400 Milligram Daily;		Not Reported
	Ketoprofen			S	Topical			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prevnar 13			S	Intramuscular			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817875	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238166			Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Joint Swelling; Polyarthrititis; Synovitis; Weight Decreased	Azathioprine			S	Unknown			Not Reported
	Mycophenolate Sodium			S	Unknown			Teva
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				Not Reported
	Acetaminophen			C	Oral			Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Actemra			C	Unknown			Not Reported
	Bisoprolol			C				Not Reported
	Candesartan			C				Not Reported
	Depo-Medrol			C	Intra-articular			Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported
	Sulfamethoxazole And Trimethoprim			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17817915	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1239120		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Malaise; Throat Cancer; Thrombosis	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Mycophenolate Mofetil			S	Unknown			Teva
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818373	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1237765			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Minocycline Hydrochloride			S	Unknown			Actavis	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Leflunomide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601993		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Herpes Zoster; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Lyrica	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818465	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1238099			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818499	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1239114		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Abdominal Discomfort; Drug Ineffective; Gastric Ulcer; Malaise; Throat Cancer; Thrombosis	Azathioprine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Barr
	Mycophenolate Mofetil	S	Unknown	Teva
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818723	NON-EXPEDITED			NVSC2020US141219			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Iron Overload	Jadenu			S	Unknown	Unk		Novartis
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818940	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602354		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 2.0 Years		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17818965	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605839		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
Remicade			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	12304140	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1745534			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Contraindicated Product Administered; Discomfort;	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown	25 Mbq		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hip Arthroplasty; Hypersensitivity; Infusion Related Reaction; Joint Swelling; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Pericarditis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown	And 5 Mg	Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral	25 Mg (For 11 Years)	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	11 Months	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	S	Oral		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Golimumab	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Kevzara	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Topicort [Desoximetasone]	S	Cutaneous	Not Reported
Topicort [Desoximetasone]	S		Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Salazopyrin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17042389	EXPEDITED (15-DAY)		OT	CA-ROCHE-2464645		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Pain; Red Blood Cell Sedimentation Rate Abnormal; Treatment Failure	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infliximab	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified) Powder For Solution	Not Reported
Simponi	S	Subcutaneous Solution	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Desoximetasone	C	Unknown	Not Reported
Methotrexate	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17063042	EXPEDITED (15-DAY)		OT	CA-ROCHE-2471629			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Exposure During Pregnancy; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Plaquenil [Hydroxychloroquine Sulfate]		S	Unknown				Not Reported
	Prednisone		S	Unknown				Not Reported
	Cetirizine Hydrochloride		S	Unknown				Not Reported
	Remicade		S	Intravenous (not otherwise specified)	Powder For Solution Intravenous			Not Reported
	Simponi		S	Subcutaneous				Not Reported
	Simponi		S	Subcutaneous				Not Reported
	Sulfasalazine		S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17721471	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1227414		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	2-3 Cp Per Day:400 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17804815	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3410200-00		86 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide;	Kaletra			S	Oral			Not Reported
Depressed Mood;	Hidroxicloroquina			S	Unknown			Not Reported
Hypertransaminaemia;	Azitromicina			S	Unknown			Not Reported
Long Qt Syndrome	Metilprednisolona			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818370	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603021			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gait Disturbance; Pain	Rituxan	S	Intravenous drip	Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Unknown	Not Reported
	Ceftazidime	S	Unknown	Not Reported
	Piperacillin/Tazobactam	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Rosuvastatin	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported
	Lasix [Furosemide]	S	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Acetaminophen	C		Not Reported
	Actonel	C		Not Reported
	Amiodarone	C	Unknown	Not Reported
	Diphenhydramine	C		Not Reported
	Eprex	C	Intravenous (not otherwise specified)	Not Reported
	Escitalopram	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Insulin Lispro	C		Not Reported
	Januvia	C		Not Reported
	Metformin	C	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Metoprolol	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Piperacillin/Tazobactam	C		Not Reported
	Potassium Chloride	C		Not Reported
	Risedronate Sodium	C		Not Reported
	Slow-K	C		Not Reported
	Tylenol	C		Not Reported
	Ventolin [Salbutamol]	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818429	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601015			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Off Label Use; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818446	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602195		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Arthropathy; Delirium; Dislocation Of Vertebra; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Infection; Off Label Use; Rheumatoid Arthritis; Seronegative Arthritis; Spinal Disorder; Therapeutic Product Effect Decreased; Type 2 Diabetes Mellitus; Wound Infection	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Simponi	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Naprosyn [Naproxen]	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818450	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603092			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatomyositis; Dysphagia; Gastrointestinal Disorder; Hepatitis; Muscle Disorder; Skin Disorder	Cellcept [Mycophenolate Mofetil]			S	Unknown	Therapy Duration: 61.0		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myfortic			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818458	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601809		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Arthralgia; Chronic Sinusitis; Diverticulum; Drug Ineffective; Haemochromatosis; Impaired Work Ability; Irritable Bowel Syndrome; Joint Swelling; Nausea; Osteoporosis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818807	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083- 3414053-00		77 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598521		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosis; Wheezing	Actemra			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Unknown			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Diclofenac Sodium			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Folic Acid			S	Subcutaneous			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818879	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605911			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Azathioprine			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818888	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601616		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Rituximab			S	Intravenous (not			Not Reported	
Cartilage Atrophy; Drug					otherwise specified)				
Ineffective; Joint Swelling;	Humira			S	Subcutaneous			Not Reported	
Nausea; Nephrotic	Methotrexate			S	Unknown			Not Reported	
Syndrome; Off Label Use;	Methotrexate			S	Unknown			Not Reported	
Periorbital Oedema; Renal	Orencia			S	Intravenous (not			Not Reported	
Disorder; Skin Erosion;					otherwise specified)				
Therapeutic Product Effect	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported	
Decreased; Wrist	Sulfate]								
Deformity	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported	
	Sulfate]								
	Leflunomide			C				Not Reported	
	Naproxen			C				Not Reported	
	Sulfasalazine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819004	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601685			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective;	Rituximab			S	Intravenous (not			Not Reported	
Goitre; Headache;					otherwise specified)				
Inflammation; Joint	Actemra			S	Unknown			Not Reported	
Swelling; Knee	Apo-Prednisone			S	Oral			Not Reported	
Arthroplasty; Lower	Apo-Prednisone			S	Oral			Not Reported	
Respiratory Tract	Enbrel			S	Subcutaneous			Not Reported	
Infection; Musculoskeletal	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Pain; Musculoskeletal	Methotrexate			S	Oral			Not Reported	
Stiffness; Nasopharyngitis;									
Nephrolithiasis; Off Label	Methotrexate			S	Unknown			Not Reported	
Use; Pain; Pain In									
Extremity; Peripheral									
Swelling; Rheumatoid									

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Arthritis; Swelling	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601843			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe Solution Subcutaneous		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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			otherwise specified)	
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Folic Acid	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819015	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598559		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Ineffective; Fall; Fatigue; Femur Fracture; Impaired Healing; Intentional Product Use Issue; Joint Laxity; Multiple Fractures; Off Label Use; Osteoporosis; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819081	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895764			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Joint Swelling; Nausea; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Bacitracin	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Neomycin Sulfate	S	Unknown	Not Reported
	Polymyxin B Sulfate	S	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819232	EXPEDITED (15-DAY)		OT	BN-ACCORD-182780		67 YR	Male	BRN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Hydroxychloroquine			S		400 Mg Twice Daily Day-1 And 200 Mg Twice Daily Day-2 To 5		Not Reported
	Lopinavir/Ritonavir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819257	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599836		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Condition Aggravated; Cough; Drug Ineffective; Headache; Off Label Use; Rheumatoid Arthritis; Treatment Failure; Viral Infection	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

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Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602945			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819335	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202004005747			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia; Pain In Extremity; Therapeutic Product Effect Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Humira			S	Subcutaneous	Unk, Citrate Free (1 In 2 Wk)		Not Reported	
	Methotrexate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819381	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1239130			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Barr	
	Methotrexate			S				Barr	
	Minocycline			S	Unknown			Actavis	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	
	Leflunomide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819383	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601269		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amyotrophic Lateral Sclerosis; Gait	Actemra			S	Intravenous (not			Not Reported	

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Disturbance; Multiple System Atrophy; Off Label Use; Rheumatoid Arthritis	Rituximab	S	otherwise specified)	Not Reported
	Enbrel	S	Intravenous drip	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Oral	Not Reported
	Xeljanz	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17819384	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601291		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported

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Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Fosamax	S	Oral	Not Reported
Fosamax	S		Not Reported
Folic Acid	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Cetirizine	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Certolizumab Pegol	S	Subcutaneous	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Fosamax	S	Intracavernous	Not Reported
Fosamax	S		Not Reported
Fosamax	S	Unknown	Not Reported
Fosamax	S		Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

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23-May-2020	17819386	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606795		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Rabeprazole Sodium			C	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17350897	EXPEDITED (15-DAY)		DE	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020-BI-00		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Chest Discomfort	Atrovent	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Flovent	S	Unknown	Not Reported
	Albuterol Sulfate And Ipratropium Bromide	S	Unknown	Not Reported
	Lasix [Furosemide Sodium]	S	Unknown	Not Reported
	Lipitor	S	Unknown	Not Reported
	Losec [Omeprazole Magnesium]	S	Oral	Not Reported
	Metformin	S	Oral	Not Reported
	Nitrazadon	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Salmeterol Xinafoate	S	Unknown	Not Reported
	Tylenol	S	Unknown	Not Reported
	Atorvastatin Calcium	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17819810	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605534		52 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective; Enterocolitis; Off Label Use; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Prednisone			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2020	17819817	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599451			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Off Label Use; Onychomadesis; Onychomycosis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Arava			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	12855891	EXPEDITED (15-DAY)		HO	CA-ROCHE-1842514		65 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Naproxen			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			S	Oral	Therapy Duration: 6 Days		Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Prednisone Acetate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0		Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 731.0		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	13161522	EXPEDITED (15-DAY)		DS, HO, OT	CA-CELGENEUS-CAN-2016047597		41 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Otezla			S	Oral	60 Milligram		Celgene	
Alanine Aminotransferase	Otezla			S	Oral	60 Milligram		Celgene	
Abnormal; Alanine	Otezla			S	Oral			Celgene	
Aminotransferase	Otezla			S	Oral			Celgene	
Increased; Arthralgia;	Otezla			S	Oral	120 Milligram		Celgene	
Arthritis; Arthritis;	Otezla			S	Oral			Celgene	
Arthropathy; Aspartate	Otezla			S	Oral			Celgene	
Aminotransferase	Otezla			S	Oral			Celgene	
Increased; Aspartate	Adalimumab			S	Subcutaneous			Not Reported	
Aminotransferase	Certolizumab Pegol			S	Subcutaneous			Not Reported	
Increased; Basal Cell	Certolizumab Pegol			S	Unknown			Not Reported	
Carcinoma; Blood	Ciclosporin			S	Oral	.6 Milligram		Not Reported	
Creatinine Increased;	Ciclosporin			S	Unknown			Not Reported	
Blood Parathyroid	Ciclosporin			S	Unknown			Not Reported	
Hormone Decreased;	Ciclosporin			S	Unknown			Not Reported	
Blood Pressure Systolic	Ciclosporin			S	Unknown			Not Reported	
Increased; C-Reactive	Ciclosporin			S	Unknown			Not Reported	
Protein Abnormal; C-	Ciclosporin			S	Unknown			Not Reported	
Reactive Protein	Ciclosporin			S	Oral			Not Reported	
Abnormal; C-Reactive	Ciclosporin			S	Oral			Not Reported	
Protein Increased;	Ciclosporin			S	Unknown			Not Reported	
Contraindicated Product	Ciclosporin			S	Unknown			Not Reported	
Administered; Decreased	Ciclosporin			S	Oral			Not Reported	
Appetite; Diarrhoea; Drug	Etanercept			S	Subcutaneous			Not Reported	
Eruption; Drug	Etanercept			S	Unknown			Not Reported	
Hypersensitivity; Drug	Etanercept			S	Unknown			Not Reported	
Ineffective; Drug	Golimumab			S	Subcutaneous			Not Reported	
Intolerance; Enthesopathy;	Infliximab			S	Intravenous drip	400 Milligram		Not Reported	
Enthesopathy; Erythema;	Sulfasalazine			S	Endocervical			Not Reported	
Erythema; Erythema;	Sulfasalazine			S	Unknown	500 Milligram		Not Reported	
Fatigue; Fear Of Injection;	Sulfasalazine			S	Unknown			Not Reported	
General Physical Health									
Deterioration; Granuloma									
Skin; Headache;									
Hypercalcaemia;									
Hypersensitivity;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity;	Ustekinumab	S	Subcutaneous		Not Reported
Inflammation; Infusion	Ustekinumab	S	Unknown		Not Reported
Related Reaction;	Abatacept	S	Subcutaneous		Not Reported
Insomnia; Joint Injury;	Enbrel	S	Subcutaneous		Not Reported
Joint Swelling; Loss Of	Enbrel	S	Unknown		Not Reported
Personal Independence In	Enbrel	S	Unknown		Not Reported
Daily Activities; Loss Of	Enbrel	S	Unknown	25 Milligram	Not Reported
Personal Independence In	Enbrel	S	Unknown	25 Milligram	Not Reported
Daily Activities; Loss Of	Humira	S	Subcutaneous		Not Reported
Personal Independence In	Stelara	S	Subcutaneous		Not Reported
Daily Activities;	Simponi	S	Subcutaneous		Not Reported
Musculoskeletal Stiffness;	Orencia	S	Unknown		Not Reported
Nausea; Off Label Use;	Orencia	S	Subcutaneous		Not Reported
Pain; Panniculitis;	Cimzia	S	Subcutaneous		Not Reported
Peripheral Swelling;	Sulfamethoxazole	S	Oral	600 Milligram	Not Reported
Psoriatic Arthropathy;	Motrin	S	Oral	600 Milligram	Not Reported
Rash; Rash Pruritic; Red	Motrin	S	Oral	6 Dosage Forms	Not Reported
Blood Cell Sedimentation	Motrin	S	Oral	600 Milligram	Not Reported
Rate; Red Blood Cell	Motrin	S	Oral	600 Milligram	Not Reported
Sedimentation Rate	Motrin	S	Oral	600 Milligram	Not Reported
Increased; Rheumatoid	Motrin	S	Oral	600 Milligram	Not Reported
Arthritis; Rheumatoid	Motrin	S	Oral	600 Milligram	Not Reported
Nodule; Skin Necrosis;	Alendronate Sodium	S	Unknown	70 Milligram	Not Reported
Skin Ulcer; Synovitis;	Arava	S	Unknown	20 Milligram	Not Reported
Tendonitis; Tenosynovitis;	Celebrex	S	Oral	200 Milligram	Not Reported
Therapy Non-Responder;	Codeine	S	Unknown		Not Reported
Tongue Disorder;	Cosentyx	S	Unknown		Not Reported
Treatment Failure; Ulcer;	Hydroxychloroquine	S	Unknown		Not Reported
Urticaria	Remicade	S	Intravenous drip		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	Intravenous drip	2000 Milligram	Not Reported
Rituximab	S	Unknown		Not Reported
Tocilizumab	S	Unknown	360 Milligram	Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous	15 Milligram	Not Reported
Methotrexate	S	Subcutaneous	17.5 Milligram	Not Reported
Methotrexate	S	Subcutaneous	10 Milligram	Not Reported
Methotrexate	S	Oral	4 Dosage Forms	Not Reported
Methotrexate	S	Subcutaneous	12.5 Milligram	Not Reported
Apo Ibuprofen	S	Oral	600 Milligram	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Colchicine	C	Oral	.6 Milligram	Not Reported
Folic Acid	C	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Methotrexate Sodium	C	Oral	4.0 Dosage Forms	Not Reported
Methotrexate Sodium	C	Unknown	10 Milligram	Not Reported
Methotrexate Sodium	C	Oral		Not Reported
Methotrexate Sodium	C	Unknown	2.5 Milligram	Not Reported
Mogadon	C	Unknown	5 Milligram	Not Reported
Oxyneo	C	Oral	40 Milligram Er	Not Reported
Oxyneo	C	Oral	10 Milligram	Not Reported
Oxyneo	C	Unknown	40 Milligram Er	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Oxyneo	C	Unknown	10 Milligram	Not Reported
Uloric	C	Oral	160 Milligram	Not Reported
Uloric	C	Oral	80 Milligram	Not Reported
Uloric	C	Unknown	80 Milligram	Not Reported
Uloric	C	Unknown		Not Reported
Oxycodone Hydrochloride	C	Unknown	40 Milligram	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oxycodone Hydrochloride	C	Unknown	10 Milligram	Not Reported
Oxycodone Hydrochloride	C	Unknown		Not Reported
Febuxostat	C	Unknown	160 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown		Not Reported
Nitrazepam	C	Unknown	5 Milligram	Not Reported
Nitrazepam	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Gravol	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Acide Folique	C	Unknown		Not Reported
Actonel	C	Oral	35 Milligram	Not Reported
Naproxen	C	Unknown	500 Milligram	Not Reported
Oxycodone	C	Unknown	10 Milligram	Not Reported
Oxycodone	C	Unknown	40 Milligram	Not Reported
Oxycodone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Vitamin D3	C	Oral	2000 Iu (International Unit)	Not Reported
Xeljanz	C	Unknown		Not Reported
Cannabis Sativa	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	13182650	EXPEDITED (15-DAY)		OT	CA-ROCHE-1747445		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Hypersensitivity; Impaired Work Ability; Loss Of	Celebrex			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Personal Independence In Daily Activities;	Methotrexate	S	Oral		Not Reported
Rheumatoid Arthritis;	Methotrexate	S	Subcutaneous		Not Reported
Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete;	Actemra	S	Intravenous (not otherwise specified)		Not Reported
Viral Upper Respiratory Tract Infection	Leflunomide	S	Unknown		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Xeljanz	C	Oral	On Hold	Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	14763969	EXPEDITED (15-DAY)		OT	CA-ROCHE-2104641		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Vaccine;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Condition Aggravated;	Enbrel			S	Subcutaneous			Not Reported
Diarrhoea; Drug Ineffective; Fall;	Humira			S	Subcutaneous			Not Reported
Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
Laryngeal Disorder;	Methotrexate Sodium			S	Oral			Not Reported
Larynx Irritation; Nausea;	Methotrexate Sodium			S	Subcutaneous			Not Reported
Product Use Issue;	Methotrexate Sodium			S	Oral			Not Reported
Pruritus; Treatment Failure; Weight Decreased	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Zostavax			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	15237821	EXPEDITED (15-DAY)		CA, DE	DE-ROCHE-2162345			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Septal Defect; Congenital Cardiovascular Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Low Birth Weight Baby; Premature Baby; Truncus Arteriosus Persistent; Ventricular Septal Defect	Ezetimibe			S	Transplacental	From Gestational Week 0-14		Not Reported
	Clexane			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 200 Mg, Frequency: Once Daily From		Not Reported
	Heparin Lmw			S	Transplacental			Not Reported
	Xarelto			S	Transplacental	From Gestational Week 0-5		Not Reported
	Hydroxychloroquine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Acetylsalicylic Acid			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily100 Mg		Not Reported
	Enoxaparin			S	Transplacental	From Gestational Week 0-14		Not Reported
	Nicotine			S	Transplacental	From Gestational Week 0-14		Not Reported
	Ramipril			S	Transplacental	From Gestational Week 0-113+6		Not Reported
	Prednisolon [Prednisolone]			S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 10 Mg, Frequency: Every 2 Days From		Not Reported

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Tacrolimus	S	Transplacental	From Gestational Week 0-14	Not Reported
Tacrolimus	S			Not Reported
Pantozol [Pantoprazole Sodium Sesquihydrate]	S	Transplacental	From Gestational Week 0-14therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 40 Mg, Fr	Not Reported
Quensyl	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 400 Mg, Frequency: Once Daily	Not Reported
Salbutamol	S	Transplacental	Frequency: Daily From Gestational Week 0-14	Not Reported
Aliskiren	S	Transplacental		Not Reported
Rituximab	S	Transplacental		Not Reported
Rasilez	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 17/Jan/2012 Dose: 300 Mg, Frequency: Once Daily	Not Reported
Metamizole	S	Transplacental	From Gestational Week 0-14	Not Reported
Dalteparin Sodium	S	Transplacental		Not Reported
Novaminsulfon	S	Transplacental		Not Reported
Delix [Ramipril]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 20 Mg, Frequency: Once Daily	Not Reported
Torem [Torasemide]	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date:	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Advagraf	S	Transplacental	20/Mar/2012 Dose: 100 Mg, Frequency: Once Daily From	Not Reported
Simvastatin	S	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 Dose: 6 Mg, Frequency: Once Daily	Not Reported
Cytotec	C	Transplacental	Therapy Start Date:14/Dec/2011 Cessation Date: 20/Mar/2012 From Gestational Week 0-14	Not Reported
Cyclophosphamide	C	Transplacental	Start Date And Cessation Date: 20/Mar/2012	Not Reported
Mifegyne	C	Transplacental	3000 Mg Cumulative Start Date, Cessation Date: /Aug/2011	Not Reported
			Start Date And Cessation Date: 20/Mar/2012	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	15247879	EXPEDITED (15-DAY)		DE, HO	CA-ROCHE-2164538		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Death;	Actemra			S	Unknown			Not Reported
Deep Vein Thrombosis;	Actemra			S				Not Reported
Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Herpes	Sulfasalazine	S		Not Reported
Zoster; Intentional Product	Apo-Leflunomide	S	Unknown	Not Reported
Use Issue; Interstitial Lung	Apo-Leflunomide	S	Unknown	Not Reported
Disease; Joint Swelling;	Apo-Leflunomide	S	Unknown	Not Reported
Off Label Use; Pain;	Apo-Leflunomide	S	Unknown	Not Reported
Photosensitivity Reaction;	Enbrel	S	Subcutaneous	Not Reported
Product Use In	Enbrel	S	Unknown	Not Reported
Unapproved Indication;	Humira	S	Unknown	Not Reported
Pulmonary Embolism;	Humira	S	Subcutaneous	Not Reported
Pulmonary Thrombosis;	Humira	S	Unknown	Not Reported
Red Blood Cell	Humira	S	Unknown	Not Reported
Sedimentation Rate	Hydroxychloroquine	S	Unknown	Not Reported
Increased; Renal Failure;	Hydroxychloroquine	S	Unknown	Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown	Not Reported
Sepsis; Stomatitis;	Ilaris	S	Subcutaneous	Not Reported
Thrombosis; Urticaria	Ilaris	S	Intravenous (not otherwise specified)	Not Reported
	Ilaris	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cannabis Sativa	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Minocycline	S	Unknown	Not Reported
Minocycline Hydrochloride	S	Unknown	Not Reported
Oxycodone	S	Unknown	Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Oxyquinoline Sulfate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Gold	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Lyrica	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	16808742	EXPEDITED (15-DAY)		OT	CA-ROCHE-2402077		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Therapeutic Product Effect Incomplete	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17317853	EXPEDITED (15-DAY)		OT	CA-ROCHE-2529157		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Headache; Hypersensitivity; Nausea; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Acetaminophen;Codeine Phosphate			C				Not Reported
	Atacand			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Hydrodiuril			C				Not Reported
	Neurontin			C	Unknown			Not Reported
	Premarin			C				Not Reported

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	Tylenol	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Aluminium Acetate	C		Not Reported
	Benzethonium Chloride	C		Not Reported
	Ergocalciferol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17746062	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020178143		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
	Nivaquine [Chloroquine Sulfate]			S	Oral	200 Mg, Daily (2-3 Tablets Per Day)		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Daily, 2-3 Tablets Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17756593	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010455			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg, Q.Wk.		Apotex	
	Actemra			S	Unknown	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, (One Every Six Weeks)		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Enbrel			S	Unknown	25 Mg, Q.O.Wk.		Not Reported	
	Methotrexate			S	Unknown	15 Mg, Q.Wk.		Not Reported	
	Methotrexate			S	Unknown	20 Mg, Q.Wk.		Not Reported	
	Plaquenil /00072602/			S	Intravenous (not	200 Mg, Bid		Not Reported	

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		otherwise specified)			
Sulfasalazine	C	Unknown	Unk		Not Reported
Wellbutrin	C	Unknown	Unk		Not Reported
Xeljanz	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17772750	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC-2020187436		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg		Pfizer
	Propranolol			S	Oral	20 Mg, Every 12 Hours		Not Reported
	Laroxyl			S	Oral	15 Drop, 1x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg, Every 12 Hours		Not Reported
	Paracetamol			C	Oral	Unk Unk, As Needed		Not Reported
	Pantoprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Oxygen			C	Respiratory (inhalation)	1 L, Every 1 Minute		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17810040	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005315			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17811826	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005312			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Septic Shock	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17811877	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005316			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myocardial Reperfusion Injury	Hydroxychloroquine			S				Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17811905	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202005005343			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myocardial Reperfusion Injury	Hydroxychloroquine			S		Unk		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17814986	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-025966		86 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Depressed Mood; Hypertransaminasaemia; Long Qt Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Kaletra			S	Unknown	Unk		Not Reported	
	Methylprednisolone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820055	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601477		68 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Methotrexate			S	Oral			Not Reported	

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Bronchitis; Cough; Drug	Methotrexate	S	Oral	Not Reported
Hypersensitivity; Drug	Rituximab	S	Unknown	Not Reported
Ineffective; Drug	Enbrel	S	Subcutaneous	Not Reported
Intolerance; Foot	Erythromycin	S	Unknown	Not Reported
Deformity; Hepatotoxicity;	Humira	S	Subcutaneous	Not Reported
Influenza Like Illness;	Hydroxychloroquine	S	Oral	Not Reported
Interstitial Lung Disease;	Hydroxychloroquine	S	Oral	Not Reported
Malaise; Mass; Nodule;	Leflunomide	S	Oral	Not Reported
Off Label Use;	Orencia	S	Unknown	Not Reported
Rheumatoid Arthritis;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Stress; Therapeutic	Sulfasalazine	S	Unknown	Not Reported
Product Effect Decreased	Xeljanz	S	Oral	Not Reported
	Wellbutrin	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Risedronate	C	Unknown	Not Reported
	Risedronate	C	Oral	Not Reported
	Ergocalciferol	C	Unknown	4000 Iu (International Unit) Not Reported
	Celebrex	C	Unknown	Not Reported
	Celebrex	C	Unknown	Not Reported
	Cannabis Sativa	C	Unknown	Not Reported
	Bupropion	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820092	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601286		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Fracture; Anti-Cyclic	Actemra			S	Unknown			Not Reported
Citrullinated Peptide	Apo-Leflunomide			S	Unknown			Not Reported
Antibody Positive;	Apo-Prednisone			S	Unknown			Not Reported
Arthralgia; Asthenia; Bone								

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Density Abnormal;	Apo-Prednisone	S	Oral	Not Reported
Decreased Appetite;	Apo-Prednisone	S	Unknown	Not Reported
Disability; Drug Ineffective;	Arava	S	Unknown	Not Reported
Headache;	Cimzia	S	Subcutaneous	Not Reported
Hypercholesterolaemia;	Enbrel	S	Subcutaneous	Not Reported
Infection; Joint Stiffness;	Gold	S	Unknown	Not Reported
Joint Swelling; Limb	Humira	S	Subcutaneous	Not Reported
Deformity; Malaise; Mood	Hydroxychloroquine	S	Unknown	Not Reported
Swings; Musculoskeletal	Indometacin	S	Unknown	Not Reported
Stiffness; Nasopharyngitis;	Indometacin	S	Unknown	Not Reported
Nausea; Neck Deformity;	Methotrexate	S	Oral	Not Reported
Neck Mass; Off Label Use;	Methotrexate	S	Subcutaneous	Not Reported
Pain; Rheumatoid Arthritis;	Methotrexate	S	Subcutaneous	Not Reported
Rheumatoid Factor	Methotrexate	S	Oral	Not Reported
Positive; Stress;	Methotrexate	S	Subcutaneous	Not Reported
Therapeutic Product Effect	Methotrexate	S	Subcutaneous	Not Reported
Decreased; Therapeutic	Methotrexate	S	Subcutaneous	Not Reported
Product Effect Incomplete;	Methotrexate	S	Subcutaneous	Not Reported
Treatment Failure;	Methotrexate	S	Oral	Not Reported
Vomiting	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Folic Acid	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820095	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1239435		23 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis; Enterovirus Infection; Off Label Use	Prednisolone			S	Unknown			Actavis	
	Prednisolone			S	Unknown	In July 2017 At The Time Of Presentation For The 1st Time		Actavis	
	Prednisolone			S	Oral	In 2018, At The Time Of Flare Of Sle Administered After Methylprednisolone		Actavis	
	Prednisolone			S	Oral	Final Dose After Tapered Down By 5mg/Week		Actavis	
	Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown	In July 2017 At The Time Of Presentation For The 1st Time; Later Discontinued		Not Reported	
	Mycophenolate Mofetil			S	Unknown	After Azathioprine Was Stopped; Therapy Stopped In 2018 After 2en Enterovirus Event		Teva	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Rituximab			S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart		Not Reported	
	Rituximab			S	Other	First Dose: 2g/Kg Body Weight; Second Dose After 2 Weeks: 1g Infusion In 2 Doses 14 Days Apart		Not Reported	
	Immunoglobulins Nos			S	Intravenous (not otherwise specified)	2 G/Kg		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported	
	Aciclovir			C	Intravenous (not			Not Reported	

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Methylprednisolone	C	otherwise specified) Intravenous (not otherwise specified)	Not Reported

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25-May-2020	17820175	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602385		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthrodesis; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Hand Deformity; Infection; Limb Discomfort; Off Label Use; Rash; Rheumatoid Arthritis; Urticaria	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			C				Not Reported
	Prednisone			C				Not Reported
	Tofacitinib Citrate			C				Not Reported

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Viread	C	Not Reported
Amlodipine	C	Not Reported
Arava	C	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Not Reported

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25-May-2020	17820197	EXPEDITED (15-DAY)		OT	CA-ROCHE-2603590			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Exfoliative Rash; Fatigue; Hepatitis; Myositis; Pruritus; Pyrexia; Swelling; Urticaria; Visual Impairment	Mycophenolate Mofetil			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820205	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600455			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820234	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600299		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Arthropathy; Crohn'S	Apo-Leflunomide			S	Oral			Not Reported
Disease; Diabetes	Apo-Leflunomide			S	Unknown			Not Reported
Mellitus; Diarrhoea; Drug	Arava			S	Oral			Not Reported
Hypersensitivity; Drug	Cimzia			S	Subcutaneous	Solution Subcutaneous		Not Reported
Ineffective; Erythema;	Enbrel			S	Unknown			Not Reported
Gastrointestinal Disorder;	Humira			S	Subcutaneous			Not Reported
Impaired Work Ability; Iron	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Deficiency Anaemia; Joint	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Effusion; Lip Ulceration;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Mobility Decreased; Mouth	Leflunomide			S	Oral			Not Reported
Ulceration;	Leflunomide			S	Unknown			Not Reported
Musculoskeletal Disorder;	Methotrexate			S	Subcutaneous			Not Reported
Off Label Use;	Methotrexate			S	Subcutaneous			Not Reported
Rheumatoid Arthritis; Skin	Methotrexate			S	Unknown			Not Reported
Warm; Spinal Stenosis;	Orencia			S	Unknown			Not Reported
Therapeutic Product Effect	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Decreased; Tuberculin	Simponi			S	Subcutaneous			Not Reported
Test Positive; Urinary	Xeljanz			S	Oral			Not Reported
Tract Infection	Gold			C	Unknown			Not Reported
	Prednisone			C	Intravenous (not			Not Reported

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820297	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602932		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Drug Ineffective; Fatigue; Glossodynia; Hypersensitivity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Folic Acid			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cortisone Acetate			S	Unknown			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Golimumab			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Winpred	S	Oral	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820305	EXPEDITED (15-DAY)		DS	CA-ROCHE-1664109		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Dermatitis Allergic; Drug Hypersensitivity; Drug Ineffective; Headache; Pain In Extremity; Rash; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Voltaren [Diclofenac]	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820341	EXPEDITED (15-DAY)		OT	CA-ROCHE-2167460		54 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Contraindicated Product Administered; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820384	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-025850		56 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo	
	Kaletra			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported	
	Interferon Beta			S	Unknown	250 Milligram, Every Other Day		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Milligram, Two Times A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820447	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-026176		11 YR	Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Off Label Use; Shock	Azithromycin			S	Unknown	Unk		Aurobindo	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Lopinavir;Ritonavir			S	Oral	Unk		Not Reported	
	Methylprednisolone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820507	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600110		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Intentional Product Use Issue; Nausea; Off Label Use; Oral Discomfort; Product Use Issue; Treatment Failure; Uveitis	Rituximab			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Unknown	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Kevzara	S	Unknown	Not Reported
Kevzara	S		Not Reported
Simponi	S	Subcutaneous	Not Reported
Tofacitinib	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Prednisone	C		Not Reported
Rabeprazole Sodium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820529	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605602			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Meloxicam	C	Oral	Not Reported
Prednisolone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820530	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599273		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia;	Actemra			S	Unknown			Not Reported
Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C-Reactive Protein	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Increased; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling;	Arava			S	Unknown			Not Reported
Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling;	Enbrel			S	Subcutaneous			Not Reported
Pneumonia Viral; Product Use Issue; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Intramuscular			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Anakinra			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ativan	C	Unknown	Not Reported
Benadryl Cold	C		Not Reported
Codeine	C		Not Reported
Darifenacin	C	Unknown	Not Reported
Desoximetasone	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Dilaudid	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Diphenhydramine	C		Not Reported
Dyclonine Hydrochloride	C		Not Reported
Furosemide	C		Not Reported
Hydromorphone	C		Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular	Not Reported
Loperamide	C	Unknown	Not Reported
Morphine Sulphate	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omniaris	C		Not Reported
Oxyneo	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Plantago Ovata	C		Not Reported
Restasis	C		Not Reported
Synthroid	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Vagifem	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820557	EXPEDITED (15-DAY)		OT	NVSC2020US140984			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Prednisone			S	Transplacental	Maternal Dose: Unknown		Novartis
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported
	Fentanyl			S	Transplacental	Maternal Dose: Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lidocaine	S	Transplacental	Maternal Dose: 2 Percent	Not Reported
Prostacyclin	S	Transplacental	Maternal Dose : Unknown	Not Reported
Bupivacaine	S	Transplacental	Maternal Dose: Unknown	Not Reported
Morphine	S	Transplacental	Maternal Dose: Unknown	Not Reported
Heparin	S	Transplacental	Maternal Dose: Unknown	Not Reported
Epinephrine	S	Transplacental	Maternal Dose: Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820565	EXPEDITED (15-DAY)	HO		CA-ROCHE-2601432			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Musculoskeletal Pain; Nausea; Neck Pain; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Rash;	Actemra			S	Unknown			Not Reported
Therapeutic Product Effect Decreased; Weight Decreased	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820577	EXPEDITED (15-DAY)	OT		CA-ROCHE-2600353		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthropathy; Back Disorder; Condition	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggravated; Cutaneous	Anakinra	S	Subcutaneous	Not Reported
Vasculitis; Drug	Apo-Leflunomide	S	Oral	Not Reported
Ineffective; Drug	Enbrel	S	Subcutaneous	Not Reported
Intolerance; Knee	Humira	S	Unknown	Not Reported
Arthroplasty; Mouth	Humira	S	Subcutaneous	Not Reported
Ulceration; Off Label Use;	Humira	S	Subcutaneous	Not Reported
Oral Mucosal Exfoliation;	Humira	S	Subcutaneous	Not Reported
Osteoarthritis; Rash;	Hydroxychloroquine	S	Unknown	Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Rheumatoid Factor	Leflunomide	S	Unknown	Not Reported
Positive; Secretion	Leflunomide	S	Unknown	Not Reported
Discharge; Spinal	Leflunomide	S	Unknown	Not Reported
Stenosis; Synovitis;	Leflunomide	S	Oral	Not Reported
Vasculitic Rash	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820644	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599668		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Adverse Event; Alopecia;	Rituxan			S	Intravenous drip			Not Reported
Anti-Cyclic Citrullinated	Enbrel			S	Subcutaneous			Not Reported
Peptide Antibody Positive;	Folic Acid			S	Unknown			Not Reported
Arthropathy; Condition	Humira			S	Subcutaneous			Not Reported
Aggravated;	Methotrexate			S	Oral			Not Reported
Contraindicated Product	Methotrexate Sodium			S	Oral			Not Reported
Administered; Drug	Orencia			S	Subcutaneous			Not Reported
Ineffective; Drug	Orencia			S	Intravenous (not			Not Reported
Intolerance; Fatigue;					otherwise specified)			
Glossodynia; Hand	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Deformity; Hepatic	Sulfate]							
Enzyme Increased;	Prednisone			S	Unknown			Not Reported
Infusion Related Reaction;								
Joint Swelling; Maternal	Prednisone			S	Unknown			Not Reported
Exposure During	Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
Pregnancy; Pain;								
Pemphigus; Product Use	Reactine [Cetirizine			S	Unknown			Not Reported
Issue; Rash; Rheumatoid	Hydrochloride]							
Arthritis; Rheumatoid	Remicade			S	Intravenous (not			Not Reported
Factor Positive; Swelling;					otherwise specified)			
Synovitis; Systemic Lupus								
Erythematous; Wound	Sarilumab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S	Subcutaneous			Not Reported
	Topicalcort			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diclofenac Sodium	S	Unknown	Not Reported
Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Cortisone Acetate	S	Oral	Not Reported
Cimzia	S	Subcutaneous	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Arava	S	Oral	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Leflunomide	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820691	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020202532		55 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Atorvastatin Calcium			S	Unknown	10 Mg, 1x/Day		Pfizer
Arthralgia; Arthritis; Blood Glucose Abnormal;	Bisoprolol			S	Unknown	2.5 Mg, 2x/Day		Not Reported
Cataract; Cholelithiasis; Dizziness; Ear Discomfort; Erythema; Facial	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	200 Mg		Not Reported
Neuralgia; Fatigue; Groin Pain; Headache; Hypotension;	Sandostatin			S	Subcutaneous	Unk		Not Reported
Inappropriate Schedule Of Product Administration; Joint Stiffness;	Sandostatin Lar			S	Intramuscular	30 Mg, Monthly		Not Reported
Labyrinthitis; Muscle Spasms; Nausea; Rheumatoid Arthritis; Visual Impairment; Vomiting	Sandostatin Lar			S	Intramuscular	30 Mg, Monthly		Not Reported
	Dapagliflozin Propanediol Monohydrate			C	Unknown	5 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820782	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020200464		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820787	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200440		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Quetiapine Arrow			S	Oral	100 Mg, 1x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820788	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020202119		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Maternal Exposure During Pregnancy; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Thrombocytopenia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Fer [Ascorbic Acid;Ferrous Chloride]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820792	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020200453		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction;	Zithromax	S	Oral	250 Mg, 1x/Day	Pfizer
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820798	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601806		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Rituximab			S	Unknown			Not Reported
Arthralgia; Drug	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Ineffective; Drug								
Intolerance; Joint Swelling;	Humira			S	Subcutaneous			Not Reported
Non-Hodgkin'S	Humira			S	Unknown			Not Reported
Lymphoma; Off Label Use;	Apo-Azathioprine			S	Unknown			Not Reported
Product Use Issue;	Arava			S	Oral			Not Reported
Rheumatoid Arthritis;	Arava			S	Oral			Not Reported
Unevaluable Event	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Minocycline			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Sulfasalazine			S				Not Reported
	Xeljanz			S	Oral			Not Reported

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Xeljanz
Minocycline Hydrochloride

S
S Unknown

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820804	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020202121		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820851	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020202110		55 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg		Pfizer
	Zithromax			S	Oral	250 Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg		Not Reported
	Esidrex			C		Unk		Not Reported
	Rocephin			C		Unk		Not Reported
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17820863	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602973		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Gastric	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

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Ulcer; Malaise; Throat Cancer; Thrombosis	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821010	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020200438		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycine Pfizer			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821037	EXPEDITED (15-DAY)		OT	CA-ROCHE-1957024		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 7 Months		Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown	Therapy Duration: 7 Months		Not Reported
	Methotrexate			S	Subcutaneous	Therapy Duration: 10 Months		Not Reported
	Plaquenil [Hydroxychloroquine			S	Oral	Therapy Duration: 2 Years		Not Reported

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Sulfate]									
Prednisone	S	Unknown							Not Reported
Sulfasalazine	S	Unknown							Not Reported
Xeljanz	S	Unknown				Therapy Duration: 4 Days			Not Reported
Apo-Prednisone	S	Unknown							Not Reported
Hydroxychloroquine	S	Unknown							Not Reported
Infliximab	S	Intravenous (not otherwise specified)							Not Reported
Infliximab	S								Not Reported
Atorvastatin Calcium	C	Unknown							Not Reported
Pantoprazole Sodium	C	Unknown							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821038	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020204019		41 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertransaminasaemia; Off Label Use; Product Use In Unapproved Indication	Zitromax Avium			S	Oral	1 Df, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2 Df, 1x/Day		Not Reported
	Kaletra			S	Oral	4 Df, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821065	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599160		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Diarrhoea; Drug Ineffective; Dyspnoea; Eye Haemorrhage; Gingival Bleeding; Headache; Liver Function Test Increased; Syncope	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Plaquenil [Hydroxychloroquine Sulfate]	S	otherwise specified)	
	Remicade	S	Oral	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C	Subcutaneous	Not Reported
	Prevacid	C		Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821119	EXPEDITED (15-DAY)		OT	US-HORIZON-PRE-0167-2020			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Growth Restriction; Maternal Exposure During Pregnancy	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821134	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANSZ PHARMA-202005005422			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine			S	Oral	400 Mg, Bid, Tablet		Concordia
	Hydroxychloroquine			S	Oral	200 Mg, Bid, Tablet		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821167	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601682			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Unknown	Not Reported
	Apo-Prednisone	S	Oral	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821185	EXPEDITED (15-DAY)		HO	CA-ROCHE-2601280		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Ankylosing Spondylitis; Arthropathy; Condition Aggravated; Demyelination; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Impaired	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastric Emptying;	Azathioprine	S	Unknown	Not Reported
Influenza; Off Label Use;	Ciclosporin	S	Unknown	Not Reported
Osteoarthritis; Renal	Enbrel	S	Subcutaneous	Not Reported
Impairment; Rheumatoid	Enbrel	S	Subcutaneous	Not Reported
Arthritis; Therapeutic	Enbrel	S	Subcutaneous	Not Reported
Product Effect Decreased;	Enbrel	S	Subcutaneous	Not Reported
Therapeutic Response	Gold	S	Intramuscular	Not Reported
Decreased	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Meloxicam	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821230	EXPEDITED (15-DAY)		LT	CA-ROCHE-2598798		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death;	Actemra			S	Unknown			Not Reported	
Arthropathy; C-Reactive	Actemra			S				Not Reported	
Protein Abnormal;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Contraindicated Product									
Administered; Deep Vein	Rituximab			S				Not Reported	
Thrombosis; Diverticulitis;	Anakinra			S	Unknown			Not Reported	
Drug Hypersensitivity;									



Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821422	EXPEDITED (15-DAY)		HO	CA-ROCHE-2598993		53 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase	Actemra			S	Unknown			Not Reported
Increased; Alopecia;	Actemra			S	Unknown			Not Reported
Arthralgia; Aspartate	Actemra			S	Unknown			Not Reported
Aminotransferase	Actemra			S	Unknown			Not Reported
Increased; Basal Cell	Rituximab			S	Intravenous drip			Not Reported
Carcinoma; Blood	Rituximab			S	Intravenous drip			Not Reported
Parathyroid Hormone	Alendronate			S	Unknown			Not Reported
Decreased; C-Reactive	Apo-Leffunomide			S	Oral			Not Reported
Protein Increased; Drug	Arava			S	Unknown			Not Reported
Eruption; Drug	Cimzia			S	Subcutaneous			Not Reported
Hypersensitivity; Drug	Codeine			S	Unknown			Not Reported
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Drug	Enbrel			S	Unknown			Not Reported
Tolerance Decreased;	Enbrel			S	Unknown			Not Reported
Erythema; Gastric	Enbrel			S	Unknown			Not Reported
Disorder; Granuloma Skin;	Enbrel			S	Unknown			Not Reported
Hypercalcaemia;	Enbrel			S	Unknown			Not Reported
Hypersensitivity;	Enbrel			S	Unknown			Not Reported
Inflammation; Infusion	Enbrel			S	Unknown			Not Reported
Related Reaction; Loss Of	Humira			S	Subcutaneous			Not Reported
Personal Independence In	Hydroxychloroquine			S	Oral			Not Reported
Daily Activities;	Hydroxychloroquine			S	Oral			Not Reported
Musculoskeletal Stiffness;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Off Label Use; Pain;	Methotrexate			S	Unknown			Not Reported
Panniculitis; Peripheral	Methotrexate			S	Subcutaneous			Not Reported
Swelling; Product Use	Methotrexate			S	Subcutaneous			Not Reported
Issue; Rash; Rash Pruritic;	Methotrexate			S	Subcutaneous			Not Reported
Red Blood Cell	Methotrexate			S	Subcutaneous			Not Reported
Sedimentation Rate	Methotrexate			S	Subcutaneous			Not Reported
Increased; Rheumatoid	Methotrexate			S	Subcutaneous			Not Reported
Arthritis; Rheumatoid	Methotrexate			S	Subcutaneous			Not Reported
Nodule; Skin Necrosis;	Methotrexate			S	Subcutaneous			Not Reported
Skin Ulcer; Therapeutic	Methotrexate			S	Unknown			Not Reported
Product Effect Decreased;	Methotrexate			S	Subcutaneous			Not Reported
Therapeutic Response	Methotrexate			S	Subcutaneous			Not Reported
Decreased; Ulcer	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Intramuscular	Not Reported
Myochrysine	S	Parenteral	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821532	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000130			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported	
	Propofol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821555	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247051		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Foetal Growth Restriction; Premature Delivery	Prednisone			S	Unknown	Unk		Sun	
	Insulin			S	Unknown	Unk		Not Reported	
	Aspirin			S	Unknown	Unk		Sun	
	Plaquenil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821576	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000132			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821614	EXPEDITED (15-DAY)		HO, OT	FR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- 12-02		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised Oedema; Pneumonia; Pseudomonas Infection; Quarantine; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Catapressan			S	Unknown	Unk		Boehringer Ingelheim	
	Perfalgan			S	Unknown	1 G, Qid If Temperature Is Greater To 38.2		Not Reported	
	Tazocilline			S	Unknown	Unk		Not Reported	
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	Unk Unk, Bid (8000 Ui)		Not Reported	
	Bactrim			S	Unknown	Unk		Not Reported	
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported	
	Rocephine			S	Unknown	Unk		Not Reported	
	Mucomyst [Acetylcysteine]			S	Unknown	1 Df, Qid (Sachet Sng)		Not Reported	
	Dextro [Dextromethorphan Hydrobromide]			S	Unknown	Unk		Not Reported	
	Claventin [Clavulanate Potassium;Ticarcillin Disodium]			S	Unknown	Unk		Not Reported	
	Lederfoline			S	Unknown	Unk		Not Reported	
	Tavanic			S	Unknown	500 Mg, Bid		Not Reported	
	Eupressyl			S	Unknown	Unk		Not Reported	
	Fortum [Ceftazidime]			S	Unknown	2 G, Tid		Not Reported	
	Zithromax			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported	
	Tranxene			S	Unknown	2.5 Mg Pre Hour		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821661	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000133			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Interval Abnormal	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Azithromycin Usp			S				Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821771	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601274		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Cataract; Drug Ineffective; Drug Intolerance; Glaucoma; Hernia; Herpes Zoster; Off Label Use; Therapeutic Product Effect Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Arava			C	Unknown			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	11476817	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2014-US-010624			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Carbon Monoxide Poisoning; Carpal Tunnel Syndrome; Cyst Removal; Epilepsy; Infusion; Limb Operation; Loss Of Consciousness; Post Procedural Complication; Pruritus; Sciatica; Suicidal Ideation	Xyrem			S	Oral	1.75 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Hydroxychloroquine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	12370997	NON-EXPEDITED		OT	CA-AMGEN-CANSP2016061225		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

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Rituxan	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Prednisone	C		5 Milligram, Qd (Every 24 Hours)	Not Reported
Prednisone	C	Unknown	10 Milligram, Bid	Not Reported
Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	12842433	EXPEDITED (15-DAY)		OT	CA-ROCHE-1841433		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Carpal Tunnel Syndrome; Condition Aggravated; Drug Ineffective; Drug Intolerance; Gait Disturbance; Hip Fracture; Intervertebral Disc Disorder; Knee Arthroplasty; Mobility Decreased; Musculoskeletal Discomfort; Nausea; Off Label Use; Pain; Rheumatoid Arthritis; Stress Fracture; Vomiting; Wrist Deformity	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Simponi			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

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Hydroxychloroquine	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Prednisone	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	1 Every 24 Hrs	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	13111752	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1876541			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Arthralgia; Aspartate	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 12 Months		Not Reported
Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Condition Aggravated; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported

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Inflammation; Infusion	Codeine	S	Unknown		Not Reported
Related Reaction; Loss Of	Humira	S	Subcutaneous	Cyclical	Not Reported
Personal Independence In	Humira	S	Subcutaneous	Solution For Injection In	Not Reported
Daily Activities; Loss Of				Pre-Filled Syringe	
Personal Independence In					
Daily Activities;	Methotrexate Sodium	S	Oral		Not Reported
Musculoskeletal Disorder;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Musculoskeletal Stiffness;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Off Label Use; Pain;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Panniculitis; Peripheral	Methotrexate Sodium	S	Unknown		Not Reported
Swelling; Product Use	Methotrexate Sodium	S	Oral		Not Reported
Issue; Rash; Rash Pruritic;	Methotrexate Sodium	S	Unknown		Not Reported
Red Blood Cell	Methotrexate Sodium	S	Unknown		Not Reported
Sedimentation Rate	Methotrexate Sodium	S	Oral		Not Reported
Increased; Rheumatoid	Methotrexate Sodium	S	Subcutaneous		Not Reported
Arthritis; Rheumatoid	Methotrexate Sodium	S	Subcutaneous		Not Reported
Nodule; Skin Necrosis;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Skin Ulcer; Therapeutic	Methotrexate Sodium	S	Subcutaneous		Not Reported
Product Effect Decreased;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Therapeutic Response	Methotrexate Sodium	S	Subcutaneous		Not Reported
Decreased; Ulcer	Methotrexate Sodium	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown	Therapy Duration: 9 Months	Not Reported
	Orencia	S	Unknown		Not Reported
	Remicade	S	Unknown	Therapy Duration: 365 Nos Powder For Intravesical Solution	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Unknown		Not Reported

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Alendronate Sodium	S	Unknown		Not Reported
Alendronate Sodium	S	Unknown		Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral	Film-Coated Tablet	Not Reported
Leflunomide	S	Oral		Not Reported
Leflunomide	S	Oral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Subcutaneous		Not Reported

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Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous		Not Reported
Alendronic Acid	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral	7300 Days	Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Simponi	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Humira	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Ciclosporin	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown	For 2 Months	Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Xeljanz	C			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	13147472	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840907			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Erosion; Drug Ineffective; Joint Swelling; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Oral	8x 2.5 Mg Tablets		Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 370.0 Day(S)		Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C				Not Reported
	Xeljanz			C	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	14400613	NON-EXPEDITED		DS, OT	CA-AMGEN-CANSP2017193304		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Condition Aggravated;	Enbrel			S	Subcutaneous	Unk		Amgen
	Etanercept			S	Unknown	Unk		Amgen
	Pantoloc [Pantoprazole]			S	Unknown	40 Milligram, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Contraindicated Product Administered; Disability; Drug Hypersensitivity; Drug Ineffective; Drug-Induced Liver Injury; Haematocrit Decreased; Haemoglobin Decreased; Joint Swelling; Musculoskeletal Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis	Pantoloc [Pantoprazole]	S	Unknown	40 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Q2weeks	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1/Week	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, 1/Week	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, 1/Week	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram, Q2weeks	Not Reported
	Methotrexate Sodium	S	Oral	25 Milligram	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Q2weeks	Not Reported
	Methotrexate Sodium	S	Oral	Unk, Q2weeks	Not Reported
	Methotrexate Sodium	S	Oral	20 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	1000 Milligram, Bid	Not Reported
	Sulfasalazine	S	Oral	500 Milligram, Bid	Not Reported
	Pantoprazole Sodium Anhydrous	S	Unknown	40 Milligram, 1x/Day	Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown	40 Milligram, 1x/Day	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, 2x/Week	Not Reported
	Apo-Folic Acid	S	Unknown	5 Milligram, 2x/Week	Not Reported
	Co Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Co Atenolol	S	Unknown	20 Milligram, Qd	Not Reported
	Atenolol	S	Unknown	25 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Oral	100 Milligram, Qd	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, Bid	Not Reported
	Naprosyn [Naproxen]	S	Oral	500 Milligram, 2x/Day	Not Reported
	Naprosyn [Naproxen]	S	Oral	1000 Milligram, 1x/Day	Not Reported
	Naproxen	S	Oral	100 Milligram, Qd	Not Reported
	Naproxen	S	Oral	500 Milligram, Qd	Not Reported
	Naproxen	S	Oral	500 Milligram, Qd	Not Reported
	Palafer Cf	S	Unknown	Unk, Qd	Not Reported
	Plaquenil [Hydroxychloroquine]	S	Unknown	200 Milligram, Bid	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfate]					
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	400 Milligram, Qd		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	40 Milligram, Qd		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	200 Milligram, Bid		Not Reported
Pantoprazole Teva	S	Unknown	40 Milligram, 1x/Day		Not Reported
Pantoprazole Teva	S	Unknown	Unk		Not Reported
Arava	S	Oral	20 Milligram, Qd		Not Reported
Arava	S	Oral	20 Milligram, Qd		Not Reported
Arava	S	Oral	Unk		Not Reported
Leflunomide	S	Oral	20 Milligram, 1x/Day		Not Reported
Humira	S	Subcutaneous	Unk		Not Reported
Orencia	S	Unknown	Unk, Qd		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk		Not Reported
Orencia	S	Unknown	Unk		Not Reported
Adalimumab	S	Subcutaneous			Not Reported
Abatacept	S	Unknown	Unk		Not Reported
Ascorbic Acid	S	Unknown	Unk, 1x/Day		Not Reported
Ferrous Fumarate	S	Unknown	Unk		Not Reported
Folic Acid	S	Unknown	5 Milligram, Bid		Not Reported
Folic Acid	S	Unknown	5 Milligram, 2 Times/Wk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	400 Milligram, Qd		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, 2x/Day		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, 1x/Day		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Unk		Not Reported
Hydroxychloroquine Sulfate	S	Unknown	40 Milligram, Qd		Not Reported
Ferrous Fumarate;Folic Acid	S	Unknown	Unk, 1x/Day		Not Reported
Remicade	S	Unknown	Unk		Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Naproxen Sodium	S	Unknown	1000 Milligram, 1x/Day	Not Reported
Naproxen Sodium	S	Unknown	500 Milligram, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	100 Milligram, 2x/Day	Not Reported
Naproxen Sodium	S	Unknown	1000 Milligram, 1x/Day	Not Reported
Hydroxychloroquine	S	Unknown	400 Milligram, Weekly	Not Reported
Hydroxychloroquine	S	Unknown	40 Milligram, Weekly	Not Reported
Palafer	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	S	Unknown	40 Milligram, 1x/Day	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Celebrex	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	200 Milligram, Qd	Not Reported
Prednisone	C		5 Milligram, Qd	Not Reported
Celecoxib	C	Oral	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	14692329	EXPEDITED (15-DAY)		OT	US-UCBSA-2018012947			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete; Tuberculosis	Cimzia			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Simponi			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Arava			S		Unk		Not Reported
	Tofacitinib			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	15108403	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2018CA0760			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Joint Swelling; No Adverse Event; Rheumatoid Arthritis; Treatment Failure	Anakinra			S	Subcutaneous			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gold			S	Intramuscular			Not Reported	
	Imuran			S				Not Reported	
	Leflunomide			S				Not Reported	
	Methotrexate			S				Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Etanercept			S				Not Reported	
	Apo-Hydroxyquine			S				Not Reported	
	Methotrexate Sodium			S				Not Reported	
	Apo-Hydroxyquine			S				Not Reported	
	(Hydroxychloroquine Sulfate)								
	Rituxan (Rituximab)			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade (Infliximab)			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Vaginal			Not Reported	
	Sulfasalazine			C	Unknown			Not Reported	
	Wellbutrin			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	15108415	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0742		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Kineret			S	Unknown			Not Reported	
Adverse Event;	Celebrex			S	Unknown			Not Reported	
Arthropathy; Condition	Enbrel			S	Subcutaneous			Not Reported	
Aggravated;	Enbrel			S				Not Reported	
Contraindicated Product	Humira			S	Subcutaneous			Not Reported	
Administered; Deformity;	Methotrexate			S	Unknown			Not Reported	
Diarrhoea; Disease	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Progression; Drug	Plaquenil			S	Unknown			Not Reported	
Ineffective; Drug	Sulfasalazine			S	Unknown			Not Reported	
Interaction; Embolism;	Warfarin			S	Unknown			Not Reported	
Fear; Fine Motor Skill	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Dysfunction; Finger									
Deformity; Hand									
Deformity; Impaired									
Healing; Musculoskeletal									
Disorder; Nausea; Off									
Label Use; Pain; Rash;									
Rheumatoid Arthritis;									
Swelling; Therapeutic									
Product Effect Decreased;									
Therapeutic Product Effect									
Incomplete									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	15327973	EXPEDITED (15-DAY)		OT	CA-ROCHE-2176030		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Actemra			S	Unknown			Not Reported	
Adverse Drug Reaction;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
Adverse Event; Adverse	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
Reaction; Arthralgia;									
Contraindicated Product									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Administered; Drug			otherwise specified)	
Ineffective; Dyspepsia;	Rituxan	S	Intravenous drip	Not Reported
Fatigue; Gastric Disorder;	Rituxan	S	Unknown	Not Reported
General Physical Health	Arava	S	Oral	Not Reported
Deterioration; Insomnia;	Arava	S	Unknown	Not Reported
Joint Swelling; Malaise;	Cimzia	S	Subcutaneous	Not Reported
Nausea; Off Label Use;	Cimzia	S	Unknown	Not Reported
Pain; Product Use In	Enbrel	S	Unknown	Not Reported
Unapproved Indication;	Enbrel	S	Unknown	Not Reported
Rash; Rheumatoid	Humira	S	Subcutaneous	Not Reported
Arthritis; Sleep Disorder	Humira	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Minocycline	S	Unknown	Not Reported
	Myochrysine	S	Parenteral	Not Reported
	Myochrysine	S	Unknown	Not Reported
	Myochrysine	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Otezla	S	Unknown	Not Reported
	Otezla	S	Oral	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Minocin	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	C	Unknown	Therapy Duration: 4 Years	Not Reported
Methotrexate Sodium	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Prednisone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	15384496	EXPEDITED (15-DAY)	HO		CA-ROCHE-2181774		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Limb Deformity; Loose Body In Joint; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	15415983	EXPEDITED (15-DAY)	OT		CA-ROCHE-2186768			Female	CAN

FDA Adverse Event Reporting System

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; General Symptom; Neck Pain; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Mobicox			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	16079901	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2019- 05867			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Arthropathy; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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Antibody; Human	Methotrexate	S	Subcutaneous		Not Reported
Antichimeric Antibody Positive; Juvenile	Methotrexate	S	Subcutaneous		Not Reported
Idiopathic Arthritis; Loss Of Personal Independence	Naproxen	S	Unknown	Unknown	Not Reported
In Daily Activities; Mobility Decreased; Nausea; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Underdose; Vomiting; Wheelchair User	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Prednisone	S	Oral		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Actemra	S	Intravenous (not otherwise specified)		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Apo-Prednisone	S	Oral		Not Reported
	Gamastan	S	Intravenous (not otherwise specified)	Liquid Intramuscular	Not Reported
	Humira	S	Subcutaneous	Solution Subcutaneous, Dose- Unknown	Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Naproxen Sodium	S	Unknown	Unknown	Not Reported
	Tetanus Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Unknown.	Not Reported
	Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular, Dose- Unknown	Not Reported
	Triamcinolone Acetonide	S			Not Reported
	Triamcinolone Hexacetonide	S	Intra-articular	Unknown	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	16645866	EXPEDITED (15-DAY)		OT	CA-SA-2019SA202728			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Glossodynia; Hip Arthroplasty; Knee Arthroplasty; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Plaquenil			S	Unknown			Sanofi
	Arava			S	Unknown			Sanofi
	Diclofenac Sodium			S	Unknown			Not Reported
	Folic Acid			S	Unknown	1 Mg		Not Reported
	Prednisone			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	16714551	EXPEDITED (15-DAY)		OT	PHHY2019DE188505			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia;	Ramipril			S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval		Not Reported

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Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Omeprazole	S	Oral	1 Df, Qd (1 Df, 2x/Day (1 - 0 - 1))	Novartis
	Pregabalin	S	Unknown	3 Df, Qd	Not Reported
	Apixaban	S	Unknown	2 Df (1 Dosage Form, Bid (1-0-1))	Not Reported
	Apixaban	S	Unknown	5 Mg, Qd (2.5 Milligram, Bid)	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported
	Ambrisentan	S	Unknown	30 Mg, Qd (Film Coated Tablet)	Not Reported
	Ambrisentan	S	Unknown	1 Df, Qd	Not Reported
	Quensyl	S	Unknown	2 Df, Qd (1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval)	Not Reported
	Quensyl	S	Unknown	1 Df, Bid (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval	Not Reported
	Spasmolyt	S	Unknown	30 Mg, Qd (Number Of Separate Dosages: 1 Number Of Units In The Interval: 1 Definition Of The Interv	Not Reported
	Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
	Eliquis	S	Unknown	2 Df, Qd	Not Reported
	Roactemra	S	Subcutaneous	162 Milligram, Qwk	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra	S	Unknown	162 Mg, Qw	Not Reported
	Volibris	S	Oral	30 Mg, Qd	Not Reported
	Volibris	S	Oral	1 Df, Qd	Not Reported
	Lyrica	S	Unknown	300 Mg, Qd (100 Milligram, Tid)	Not Reported
	Lyrica	S	Unknown	100 Milligram, Tid	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17090518	NON-EXPEDITED			US-UCBSA-2018026206			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Rash	Cimzia			S		Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Methotrexate			S	Oral	Unk		Not Reported	
	Methotrexate			S		Injection		Not Reported	
	Plaquenil			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17218475	EXPEDITED (15-DAY)		OT	GB-STRIDES ARCOLAB LIMITED- 2019SP013302		23 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Behaviour Disorder; Confusional State; Headache; Infection; Liver Function Test Abnormal; Meningitis Enteroviral; Neck Pain; Off Label Use; Photophobia; Pyrexia; Speech Disorder; Viral Upper Respiratory Tract Infection; Vomiting	Mycophenolate Mofetil			S	Unknown	Unk		Strides	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	150 Milligram		Not Reported	
	Prednisolone			S	Unknown	Unk		Not Reported	
	Prednisolone			S	Unknown	7.5 Milligram Per Day		Not Reported	
	Prednisolone			S	Oral	40 Milligram		Not Reported	
	Prednisolone			S	Unknown	Weaned By 5 Mg Per Week To 5 Mg Daily		Not Reported	
	Rituximab			S	Unknown	375 Mg/M2 In 2 Doses 14 Days Apart		Not Reported	
	Rituximab			S	Unknown	Unk		Not Reported	
	Rituximab			S	Unknown	1 G Infusion In 2 Doses 14 Days Apart		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17259819	EXPEDITED (15-DAY)		OT	CA-ROCHE-2514963		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17337625	EXPEDITED (15-DAY)		OT	CA-ROCHE-2532612			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

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Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17465267	EXPEDITED (15-DAY)		OT	IT-ROCHE-2556901		43 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Pyrexia	Mycophenolate Mofetil			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown	Unk Unk (7.5 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (50 Mg Qd, Tapering Dose)		Not Reported
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported
	Prednisone			S	Unknown	Unk Unk (15 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk (25 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (10 Mg Qd, Dose Tapering)		Not Reported
	Prednisone			S	Unknown	Unk Unk (12.5 Mg Qd, Dose Tapering)		Not Reported

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Envarsus	S	Unknown	Not Reported
Belimumab	S	Unknown	Not Reported
Belimumab	S	Unknown	Not Reported
Belimumab	S	Unknown	Not Reported
Rituximab	C	Unknown Unk	Not Reported
Methylprednisolone	C	Unknown Unk (Pulses)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17559409	EXPEDITED (15-DAY)		DS	CA-ROCHE-2568722		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Fracture; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthralgia; Asthenia; Bone Density Abnormal; Decreased Appetite; Disability; Drug Ineffective; Drug Intolerance; Headache; Hypercholesterolaemia; Infection; Joint Stiffness; Joint Swelling; Limb Deformity; Malaise; Mood Swings; Musculoskeletal Stiffness; Nasopharyngitis; Nausea; Neck Deformity; Neck Mass; Pain; Rheumatoid Arthritis; Rheumatoid Factor Positive; Stress; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Indocid [Indometacin]			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Gold (198 Au) Colloidal			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Gold	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Cymbalta	C	Oral	Not Reported
	Folic Acid	C		Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17694944	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2020-011287		45 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mycobacterium Marinum Infection	Prednisolone			S	Oral	Permanent 1-0-0		Not Reported
	Prednisolone			S	Oral	Intermittent Usage; Low-Dose; Two Weeks Before Presentation		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Prednisolone			S	Oral	Flare Medication 1-0-0		Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Oral	Intermittent Usage 1-0-0		Not Reported
	Sulfasalazine			S	Oral	2-0-2		Not Reported
	Hydroxychloroquine			S	Oral	1-0-1		Not Reported
	Metoprolol			C				Not Reported
	Amlodipine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17705408	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2020165611		45 YR	Female	DEU

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Granuloma; Infective Tenosynovitis; Mycobacterium Marinum Infection	Methotrexate Sodium			S	Subcutaneous	15 Mg, Weekly		Pfizer
	Sulfasalazine			S	Oral	2 Df, 2x/Day		Pfizer
	Prednisolone			S		Unk(Intermittent Usage Of Low-Dose Prednisolone)		Not Reported
	Prednisolone			S		20 Mg		Not Reported
	Leflunomide			S	Oral	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	40 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	30 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day(Two Weeks Before Presentation)		Not Reported
	Prednisone			S	Oral	20 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	15 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	7.5 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	5 Mg, 1x/Day		Not Reported
	Prednisone			S	Oral	4 Mg, 1x/Day		Not Reported
	Hydroxychloroquine			S	Oral	200 Mg, 2x/Day		Not Reported
	Metoprolol			C		Unk		Not Reported
	Amlodipine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17710023	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP010277			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthralgia; C-Reactive Protein Increased; Condition Aggravated; Disability; Eye Disorder; Joint Swelling; Mobility	Leflunomide			S	Unknown	20.0 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	400.0 Mg, Qd		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Mg, Q.Wk.		Not Reported

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Decreased; Musculoskeletal Pain; Ocular Toxicity; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Surgery; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Humira Methotrexate Orencia Plaquenil /00072602/	S S S S	Subcutaneous Oral Unknown Unknown	40.0 Mg, Q.O.Wk. 20.0 Mg, Q.Wk. 125.0 Mg, Q.Wk. Unk	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17721825	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP010320			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Drug Ineffective; Ocular Toxicity	Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Methotrexate			S	Oral	25 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	400 Mg, Qd		Not Reported
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported
	Sulfasalazine			C	Unknown	200 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17727113	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP010387			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Drug Ineffective; Gait Disturbance; Herpes Zoster; Musculoskeletal Pain; Musculoskeletal Stiffness; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported

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Tramadol	C	Unknown	100 Mg, Qd	Not Reported
Tramacet	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17733953	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010365			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Leflunomide			S	Unknown	Unk		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17743772	EXPEDITED (15-DAY)		HO, OT	IT-VIIV HEALTHCARE LIMITED-IT2020073217		56 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema Multiforme; Off Label Use; Oral Disorder; Rash Pruritic; Rash Pustular; Rash Vesicular; Stevens-Johnson Syndrome	Abacavirsulphate+Dolutegravir+			S	Oral	1 Df, Qd		Viiv
	Lamivudine			S	Oral	1 Df, Qd		Not Reported
	Symtuza			S	Oral	400 Mg, Qd		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17746154	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010471		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Leflunomide			S	Unknown	20 Mg, Q.Wk.		Apotex	
Adverse Drug Reaction;	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Apotex	
Alanine Aminotransferase	Hydroxychloroquine			S	Unknown	9 Mg, Unk		Apotex	
Increased; Alopecia;	Methotrexate			S	Unknown	20 Mg, Unk		Not Reported	
Anxiety; Arthralgia;	Apo-Prednisone			S	Unknown	9 Mg, Unk		Apotex	
Aspartate	Actemra			S	Unknown	Unk		Not Reported	
Aminotransferase	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported	
Increased; Asthenia;	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported	
Depression; Drug	Humira			S	Subcutaneous	50 Mg, Unk		Not Reported	
Dependence; Drug	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
Ineffective; Drug	Infliximab			S	Oral	5 Mg, Bid		Not Reported	
Intolerance; Drug Use	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported	
Disorder; Fall; Fatigue;	Orencia			S	Subcutaneous	125 Mg, Q.Wk.		Not Reported	
Headache; Inflammation;	Rituximab			S	Intravenous (not otherwise specified)	9 Mg, Unk		Not Reported	
Joint Injury; Liver Disorder;	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported	
Malaise; Nausea; Off	Rituximab			S	Unknown	Unk		Not Reported	
Label Use; Pain; Red	Simponi			S	Subcutaneous	Unk, Q.M.T.		Not Reported	
Blood Cell Sedimentation	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
Rate Increased; Synovitis;	Acetaminophen			C	Unknown	500 Mg, Unk		Not Reported	
Treatment Failure	Cetirizine Hydrochloride			C	Unknown	10 Mg, Qd		Not Reported	
	Gabapentin			C	Unknown	600 Mg, Tid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17749010	EXPEDITED (15-DAY)		OT	CA-ROCHE-2590697		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Arthralgia; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dyspepsia; Gait Disturbance; Hepatic Enzyme Increased; Joint Swelling; Loss Of Personal Independence In Daily Activities; Migraine; Mobility Decreased; Nausea; Off Label Use; Pain In Extremity; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Decreased; Treatment Failure; Vomiting; X-Ray Abnormal	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 365.0		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	Therapy Duration: 6.0 Years		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 365.0		Not Reported	
	Orencia			S	Unknown	Therapy Duration: 365.0		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	

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Desoximetasone	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Pantoprazole	C		Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17749983	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP010469		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Anakinra			S	Unknown	Unk		Not Reported
	Cellcept /01275102/			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Celebrex			C	Unknown	Unk		Not Reported
	Humira			C	Unknown	Unk		Not Reported
	Methotrexate			C	Unknown	1 MI, Q.Wk.		Not Reported
	Prednisone			C	Unknown	7 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17752335	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP010525			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Rheumatoid Arthritis	Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
	Methotrexate	S	Unknown	20 Mg, Q.O.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	200 Mg, Bid	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Mg, Unk (Once In 6 Weeks)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Sulfasalazine	C	Unknown	Unk	Not Reported
	Wellbutrin	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17764352	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3398690-00		62 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Off Label Use	Lopinavir/Ritonavir			S	Oral			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Oral			Not Reported
	Piperacillina/Tazobactam			C				Not Reported
	Inhixa			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17765509	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-02071		59 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiotoxicity; Impaired	Hydroxychloroquine			S	Unknown	Unk		Lupin

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Work Ability; Myopathy	Hydroxychloroquine	S							Lupin
	Chloroquine	S	Unknown	Unk					Not Reported
	Chloroquine	S							Not Reported

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26-May-2020	17766041	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2020AP010461		8 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; C-Reactive Protein	Leflunomide			S	Oral	Unk		Apotex
Increased; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion	Hydroxychloroquine			S	Unknown	Unk		Apotex
Related Reaction; Infusion Site Reaction; Injection	Actemra			S	Unknown	Unk		Not Reported
Site Reaction; Intentional Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain; Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate	Adalimumab			S	Unknown	Unk		Not Reported
Abnormal; Red Blood Cell Sedimentation Rate	Adalimumab			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
Increased; Red Cell Distribution Width	Enbrel			S	Subcutaneous	15 Mg, Q.O.Wk.		Not Reported
Decreased; Red Cell Distribution Width	Enbrel			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Enbrel			S	Intravenous (not otherwise specified)	15 Mg, Unk		Not Reported
	Etanercept			S	Subcutaneous	15 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.Wk.		Not Reported
	Humira			S	Subcutaneous	40 Mg, Q.O.Wk.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Q.M.T.		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	200 Mg, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Q.Wk.		Not Reported
	Methotrexate			S	Subcutaneous	Unk Unk, Q.Wk.		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Orencia			S				Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported

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Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Rituximab	S	Intravenous (not otherwise specified)	420 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Tocilizumab	S	Unknown	Unk	Not Reported
	Tocilizumab	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17776898	EXPEDITED (15-DAY)		DE, OT	DE-ACCORD-181640		82 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure	Hydroxychloroquine			S	Oral	200 Mg 1-0-1		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Strength: 500 Mg ,1-0-0		Not Reported
	Azithromycin			C				Not Reported
	Piperacillin Sodium/Tazobactam Sodium			C				Not Reported
	Tazobac			C				Not Reported
	Atorvastatin			C				Not Reported
	Meropenem			C				Not Reported
	Apixaban			C				Not Reported

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26-May-2020	17787494	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1878868		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

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Humira	S	Subcutaneous	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Arava	S	Unknown	Not Reported
Azathioprine	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Apo-Azathioprine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported

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Altace	C	Unknown	Not Reported
Apo-Gabapentin	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Atorvastatin Calcium	C	Oral	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
CipraleX [Escitalopram]	C	Unknown	Not Reported
CipraleX [Escitalopram]	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Conjugated Estrogens	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Cymbalta	C	Unknown	Not Reported
Escitalopram	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Gabapentin	C	Oral	Not Reported
Hydrochlorothiazide	C	Unknown	Not Reported
Hydromorphone Hydrochloride	C	Oral	Not Reported
Hydromorphone Hydrochloride	C	Oral	Not Reported
Mupirocin	C	Topical	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Shark Liver Oil	C	Unknown	Not Reported
Tapentadol Hydrochloride	C	Unknown	Not Reported
Taro-Mupirocin	C	Topical	Not Reported
Tramacet	C	Oral	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported
Citalopram Hydrobromide	C	Unknown	Not Reported
Estrace	C	Unknown	Not Reported

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26-May-2020	17822140	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602951		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822233	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-025339		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19; Electrocardiogram Qt Prolonged	Amiodarone Arrow 200mg Scored Tablets			S	Oral	200 Milligram		Aurobindo	
	Plaquenil			S	Oral	600 Milligram		Not Reported	
	Zithromax			S	Oral	1 Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822404	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-02333		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Exposure During	Hydroxychloroquine			S	Unknown	Unk		Lupin	

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Pregnancy; Foetal Death; Foetal Growth Restriction; Hypertension; Pre- Eclampsia; Thrombotic Microangiopathy; Weight Increased	Prednisone	S	Unknown	Unk	Not Reported

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26-May-2020	17822412	EXPEDITED (15-DAY)		OT	CH-TEVA-2020-CH-1239230		72 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	800 Milligram Daily;		Teva
	Hydroxychloroquine			S	Oral	400 Milligram Daily;		Teva
	Atazanavir			S	Oral	400 Milligram Daily;		Not Reported
	Metoclopramide			S	Other	Route Of Administration : Intravenous And Oral		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Cefepime			C	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			C	Intravenous (not otherwise specified)			Not Reported
	Rocuronium			C	Intravenous (not otherwise specified)			Not Reported
	Midazolam			C	Intravenous (not otherwise specified)			Not Reported
	Propofol			C	Intravenous (not otherwise specified)			Not Reported
	Propofol			C	Intravenous (not otherwise specified)			Not Reported
	Fentanyl			C	Intravenous (not otherwise specified)			Not Reported
	Noradrenaline			C	Intravenous (not otherwise specified)			Not Reported

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Furosemide	C	Intravenous (not otherwise specified)	Not Reported
Hydrochlorothiazide	C	Oral	Not Reported
Pravastatine	C	Oral	40 Milligram Daily; Not Reported
Acetylsalicylic Acid	C	Other	100 Milligram Daily; Route Of Administration: Oral Or Intravenous Not Reported
Metoprolol	C	Oral	50 Milligram Daily; Not Reported
Torsemide	C	Oral	Not Reported
Ezetimibe	C	Oral	10 Milligram Daily; Not Reported
Allopurinol	C	Oral	300 Milligram Daily; Not Reported
Paracetamol	C	Oral	500 Milligram Daily; Not Reported
Insuline	C		Not Reported
Clexane	C	Subcutaneous	Not Reported
Duphalac	C		Not Reported
Phosphore Phoscap	C	Oral	Not Reported
Supradyne Energy	C	Oral	Not Reported

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26-May-2020	17822465	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02402		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Gestational Diabetes; Gestational Hypertension; Nephritis; Treatment Noncompliance	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Novel Labs	
	Hydroxychloroquine			S	Unknown	Unk		Lupin	
	Lovenox [Enoxaparin Sodium]			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk (Tapering Dose)		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	Unk		Not Reported	

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26-May-2020	17822616	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130913			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rash	Arava			S		Unk		Sanofi	
	Methotrexate			S	Oral	1 Df, Qw		Not Reported	
	Hydroxychloroquine Sulfate			S				Sanofi	
	Sulfasalazine			S	Oral	1 G, Qow		Not Reported	
	Prednisone			S		10 Mg, Qd		Not Reported	
	Sodium Aurothiomalate			S	Intramuscular			Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Mirtazapine			C		40 Mg, Qd		Not Reported	
	Citalopram Hydrochloride			C		40 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822635	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3418091-00		58 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral	Zitromax Avium 600 Mg Comprese Rivest		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822767	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248011		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated; Hyponatraemia	Azithromycin	S	Oral	500 Milligram, Daily	Sun
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram, Daily	Not Reported
	Symbicort Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Po...	S	Respiratory (inhalation)	2 Dosage Form, Tid	Not Reported
	Hidroxycloquina (2143a)	S	Oral	400 Mg Dia	Not Reported
	Salbutamol	S	Respiratory (inhalation)	2-2-2 Inh	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822816	EXPEDITED (15-DAY)		LT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS- 050341			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Qd		Zydus Pharm
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	400 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822845	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130998		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Neoplasm Malignant; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822847	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131032			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Leflunomide			S	Oral			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Sanofi
	Orencia			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822848	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131054			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Arava			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Actemra			S	Unknown	567 Mg, Qm		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Celebrex			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822860	EXPEDITED (15-DAY)		OT	CA-ROCHE-1889961		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis; Treatment Failure	Rituxan			S	Intravenous (not otherwise specified)	For 8 Months		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown	For 7 Months		Not Reported	
	Humira			S	Subcutaneous	For 3 To 4 Months		Not Reported	
	Leflunomide			S	Unknown	For 5 Months		Not Reported	
	Methotrexate Sodium			S	Subcutaneous	For 7 Years		Not Reported	
	Orencia			S	Unknown	For 7 Months		Not Reported	
	Orencia			S	Subcutaneous	For 7 Months		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	For 4 Years		Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous	Every 2 Weeks (For 6 Months)		Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Apo-Hydroxyquine			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Neoral			S	Oral			Not Reported	
	Neoral			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Risedronate	C	otherwise specified)	Not Reported
Arava	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822874	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131144			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Non-Hodgkin'S Lymphoma; Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Unknown	25.0 Mg		Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azathioprine			S	Unknown	100.0 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Leflunomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822875	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131129			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Fluid Retention; Joint Swelling; Memory Impairment; Pain;	Arava			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Xeljanz			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rheumatoid Arthritis;
Stomatitis; Swelling

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822876	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131104		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug-Induced Liver Injury; Hepatitis	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400.0 Mg		Sanofi
	Methotrexate			S	Subcutaneous	20 Mg, Qw		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823051	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131299			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Nephrolithiasis; Somnolence; Visual Impairment	Arava			S	Oral	20 Mg, 1 Every 1 Day		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg 2 Every 2 Days		Sanofi
	Sulfasalazine			S	Oral	2000 Mg		Not Reported
	Paracetamol			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Methotrexate			C		25 Mg, Qw		Not Reported
	Meloxicam			C				Not Reported

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Hydromorphone Hydrochloride	C	Unknown	Not Reported
Acetaminophen;Codeine Phosphate	C		Not Reported
Celebrex	C	Oral	200 Mg, Qd
Synthroid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823052	EXPEDITED (15-DAY)		HO, OT	CA-SA-2020SA131308			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein Abnormal; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Gastrointestinal Toxicity; Hepatotoxicity; Infection; Joint Injury; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Neoplasm Malignant; Pain In Extremity; Pulmonary Toxicity; Therapeutic Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Arava			S	Unknown	20 Mg		Sanofi
	Boric Acid			S	Unknown	Unk		Not Reported
	Benzalkonium Chloride			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Oral	Unk		Not Reported
	Phenylephrine Hydrochloride			S	Unknown	Unk		Sanofi
	Actemra			S	Intravenous (not otherwise specified)	8.0 Mg/Kg, Qd		Not Reported
	Benzalkonium Chloride;Diphenhydramine Hydrochloride;Phenylephrine Hydr			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Disodium Edetate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	40 Mg, Qw		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported

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Rituximab	S	Unknown	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Sodium Borate	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Unknown	10 Mg, Biw	Not Reported
Tofacitinib Citrate	S	Unknown	5 Mg, Biw	Not Reported
Tofacitinib Citrate	S	Subcutaneous	5 Mg, Biw	Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Ibuprofen	C	Oral	400 Mg	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Celebrex	C	Oral	400 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823059	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131297			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Drug Ineffective; Pneumocystis Jirovecii Pneumonia; Pulmonary Fibrosis; Synovitis	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S		Unk		Not Reported
	Sulfasalazine			S	Oral	1000 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			S		400 Mg, Qd		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823096	EXPEDITED (15-DAY)		HO	NVSC2020US120186		19 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Seizure; Weight Decreased	Trametinib			S	Oral	30 Mg		Novartis
	Trametinib			S	Oral	27 Mg		Novartis
	Comparator Hydroxychloroquine Sulfate			S	Oral	1000 Mg		Not Reported
	Comparator Hydroxychloroquine Sulfate			S	Oral	8750 Mg		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823101	EXPEDITED (15-DAY)		HO	CA-ROCHE-2599694		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)	126.0 Days		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	17.0 Days		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Gold			C				Not Reported
	Hydroxychloroquine Sulfate			C				Not Reported
	Leflunomide			C				Not Reported
	Lyrica			C				Not Reported
	Prednisone			C				Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Trazodone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823135	EXPEDITED (15-DAY)		OT	NVSC2020US142630			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature	Methylprednisolone			S	Transplacental	Unk (Mother Dose 1 G And 1 Mg/Kg)		Novartis

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Baby	Amoxicillin	S	Transplacental	Unk (Mother Dose: 500 Mg Daily)	Not Reported
	Azithromycin	S	Transplacental	Unk (Mother Dose: 500 Mg Daily)	Not Reported
	Vancomycin	S	Transplacental	Unk (Mother Dose: 750 Mg, Q8h And 1250 Mg, Q8h)	Not Reported
	Fluconazole	S	Transplacental	Unk	Not Reported
	Hydroxychloroquine	S	Transplacental	Unk (Mother Dose: 200 Mg Bid)	Not Reported
	Prednisone	S	Transplacental	Unk (Mother Doses: 70 Mg Qd, 60 Mg Qd, 50 Mg Qd, 40 Mg Qd)	Not Reported
	Cefepime	S	Transplacental	Unk (Mother Dose: 2g Q8h)	Not Reported
	Acyclovir	S	Transplacental	Unk (Mother Dose: 800 Mg Qd)	Not Reported
	Acyclovir	S	Transplacental	Unk (Mother Dose: 5 Mg/Kg, Q8h)	Not Reported
	Cyclophosphamide	S	Transplacental	Unk (Mother Dose: 500 Mg And 840 Mg)	Not Reported
	Magnesium Sulfate	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823242	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1051022		25 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Pruritus; Rash	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Plaquenil /00072603/			S	Oral	200 Milligram, Qd		Mylan
	Augmentin /00852501/			S	Oral	1 Gram, Qd		Mylan
	Clexane			C	Subcutaneous	1 Dosage Form, Qd		Mylan
	Dicloream /00372301/			C	Intramuscular	1 Dosage Form, Total		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823332	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247053			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia Neonatal; Bronchopulmonary Dysplasia; Failure To Thrive; Foetal Exposure During Pregnancy; Infantile Apnoea; Low Birth Weight Baby; Postnatal Growth Restriction; Premature Baby; Pulmonary Hypertension; Retinopathy Of Prematurity	Prednisone			S	Unknown	Unk		Sun
	Aspirin			S	Unknown	Unk		Sun
	Insulin			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823333	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603909			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis;	Mycophenolate Mofetil			S	Unknown			Not Reported
Asthenia; Astigmatism;	Belimumab			S	Unknown			Not Reported
Balance Disorder; Blood Glucose Increased;	Desoximetasone			S	Unknown			Not Reported
Cataract; Dizziness; Fall;	Fentanyl			S	Unknown			Not Reported
Fatigue; Feeling Hot;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Gastric Disorder;	Methotrexate			S	Unknown			Not Reported
Gastrointestinal Disorder;	Prednisone			S	Unknown			Not Reported
Head Discomfort;	Neurontin			C	Oral			Not Reported
Headache; Hot Flush;	Gravol			C	Unknown			Not Reported
Hypersomnia; Incorrect Dose Administered;								
Insomnia; Irritable Bowel Syndrome; Kidney Infection; Loss Of								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Personal Independence In
Daily Activities; Malaise;
Musculoskeletal Pain;
Nasal Congestion;
Nausea; Neck Pain;
Nephrolithiasis;
Oropharyngeal
Discomfort; Pain; Pain In
Extremity; Pruritus;
Raynaud'S Phenomenon;
Sepsis; Sinusitis; Sleep
Apnoea Syndrome;
Stress; Therapeutic
Product Effect Decreased;
Toxicity To Various
Agents; Upper Respiratory
Tract Congestion; Urinary
Tract Infection; Vision
Blurred; Visual Acuity
Reduced; Visual
Impairment; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823551	NON-EXPEDITED			US-PFIZER INC- 2020203536		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Peripheral Swelling	Xeljanz Xr			S		11 Mg		Pfizer	
	Hydroxychloroquine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823651	NON-EXPEDITED			US-MYLANLABS- 2020M1046393			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dizziness; Dyspnoea; Feeling Abnormal; Malaise; Product Packaging Issue;	Hydroxychloroquine Sulfate Tablets, Usp			S	Oral	Unk		Mylan	
	Hydroxychloroquine Sulfate Tablets, Usp			S				Mylan	

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Sensation Of Foreign Body	Carvedilol Tablets, Up	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823953	EXPEDITED (15-DAY)		HO, OT	CA-SAMSUNG BIOEPIS-SB-2020-17351			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Infliximab			S	Unknown			Not Reported
Antibody Test Positive;	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
Arthritis; Arthropathy;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Condition Aggravated;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Diarrhoea; Dizziness;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Drug Ineffective; Drug Intolerance; Drug Specific	Anakinra			S	Subcutaneous			Not Reported
Antibody; Human	Enbrel			S	Subcutaneous			Not Reported
Antichimeric Antibody Positive; Intentional	Enbrel			S	Subcutaneous			Not Reported
Product Use Issue;	Humira			S	Subcutaneous	Unknown, Solution Subcutaneous		Not Reported
Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Activities; Mobility Decreased; Nausea;	Immune Globulin (Human)			S	Unknown	Unknown		Not Reported
Obesity; Off Label Use;	Immune Globulin (Human)			S	Intravenous (not otherwise specified)			Not Reported
Polyarthritis; Product Use In Unapproved Indication;	Methotrexate			S	Subcutaneous			Not Reported
Psoriasis; Red Blood Cell Sedimentation Rate	Naproxen			S	Unknown	Unknown		Not Reported
Increased; Septic Shock;	Orencia			S	Intravenous (not otherwise specified)			Not Reported
Synovitis; Vomiting	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Triamcinolone		S	Unknown	Unknown			Not Reported	
	Triamcinolone Hexacetonide		S	Unknown	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824015	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247852		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Sun	
	Prednisone			S	Unknown	Unk		Mutual	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824262	NON-EXPEDITED			NVSC2020US141645			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gastrointestinal Disorder; Hypersensitivity; Urticaria	Cosentyx			S	Unknown	Unk		Novartis	
	Xeljanz Xr			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Humira			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824306	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602237		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Unknown			Not Reported	

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Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Enbrel	S	Subcutaneous	Not Reported
	Glumetza	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Lyrica	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Altace	C	Unknown	Not Reported
	Arava	C	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Codeine	C	Unknown	Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824335	EXPEDITED (15-DAY)		HO, OT	LV-PFIZER INC-2020205931		12 YR	Female	LVA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pneumonitis; Systemic Lupus	Methylprednisolone			S	Unknown	4 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythematous; Weight Decreased	Roactemra	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824360	EXPEDITED (15-DAY)		DE, OT	DE-PFIZER INC-2020206049		82 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Hydroxychloroquine			S	Oral	400 Mg, 2x/Day		Not Reported
	Tazobac			C				Not Reported
	Tazobac			C				Not Reported
	Atorvastatin			C				Not Reported
	Meropenem			C				Not Reported
	Apixaban			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824544	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2598810		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event; Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Condition Aggravated; Discomfort; Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown	9999		Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Related Reaction; Intentional Product Use Issue; Joint Swelling; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cortisone	S	Oral		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Diclofenac	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Oral		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topicorten	S	Cutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824615	EXPEDITED (15-DAY)	HO		CA-ROCHE-2600446		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Contraindicated Product Administered; Cyst; Deafness Neurosensory; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Fatigue; Gastrointestinal Disorder; Hepatic Enzyme Increased; Infection; Nausea; Osteoarthritis; Osteopenia; Pleural	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Gabapentin			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Gabapentin			S	Oral			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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Fibrosis; Pleural Thickening; Presbycusis; Renal Impairment; Skin Lesion; Sleep Disorder; Treatment Failure	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Nortriptyline	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycontin	S	Unknown Tablet (Extended-Release)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Acetaminophen	C		Not Reported
	Acetaminophen; Oxycodone Hydrochloride	C		Not Reported
	Aclasta	C	Intravenous (not otherwise specified)	Not Reported
	Actonel	C	Unknown	Not Reported
	Cholecalciferol	C		Not Reported
	D-Alpha Tocopheryl Acetate	C	Unknown	Not Reported
	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Ferrous Gluconate	C	Unknown	Not Reported
	Lomotil [Loperamide Hydrochloride]	C	Unknown	Not Reported
	Loperamide	C		Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Nasonex	C	Unknown	Not Reported
	Oxycodone Terephthalate	C		Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Perphenazine	C		Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Unknown	Not Reported

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Tylenol	C	Unknown	Not Reported
Xeljanz	C		Not Reported

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26-May-2020	17824666	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131015			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Leflunomide			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824667	EXPEDITED (15-DAY)		OT	CA-SA-2020SA130990			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis; Rheumatoid Arthritis	Leflunomide			S	Unknown	20 Mg		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 1 Every 1 Day		Sanofi
	Methotrexate			S	Unknown	20 Mg		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, 4 Every 1 Day		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported
	Acetaminophen			C	Unknown	500 Mg		Not Reported
	Hydrocortisone Valerate			C	Unknown	Unk		Not Reported

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Hydromorphone Hydrochloride	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported
Lyderm [Fluocinonide]	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	Unk	Not Reported
Naproxen	C	Unknown	250 Mg, Qd	Not Reported
Prednisone	C	Unknown	10 Mg, Qd	Not Reported
Sodium Aurothiomalate	C	Unknown	Unk Unk, Qcy	Not Reported
Sodium Aurothiomalate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2598916		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Arthralgia; Drug	Rituxan			S	Intravenous (not			Not Reported
Ineffective;					otherwise specified)			
Hypersensitivity; Joint	Prednisone			S	Unknown			Not Reported
Swelling; Maternal	Arava			S	Unknown			Not Reported
Exposure During	Cetirizine Hydrochloride			S	Unknown			Not Reported
Pregnancy;	Cetirizine			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Hydrochloride;Pseudoephedrine							
Off Label Use; Pain;	Hydrochloride							
Pemphigus; Pericarditis;	Cimzia			S	Subcutaneous			Not Reported
Product Use Issue;	Cortisone Acetate			S	Unknown			Not Reported
Rheumatoid Arthritis;	Cortisone Acetate			S	Unknown			Not Reported
Systemic Lupus	Desoximetasone			S	Oral			Not Reported
Erythematous;	Enbrel			S	Subcutaneous			Not Reported
Therapeutic Product Effect	Folic Acid			S	Unknown			Not Reported
Decreased; Treatment	Folic Acid			S				Not Reported
Failure	Fosamax			S	Unknown			Not Reported
	Golimumab			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Golimumab	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported
Salazopyrin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17824860	DIRECT					48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Impaired Work Ability; Insomnia; Pain;	Hydroxychloroquine Sulfate - Plauenil	Y		S		Quantity:1 Tablet(S);		Zydus Pharm

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Quality Issue;	Eliquis	C	Not Reported
Product Substitution Issue;	Lasix	C	Not Reported
Therapeutic Product Effect Incomplete	Telenol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825304	NON-EXPEDITED			US-UCBSA-2019010565			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Blood Glucose Increased; Eye Disorder; Migraine; Nausea; Treatment Failure	Cimzia			S				Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Orencia			S				Not Reported
	Simponi			S				Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825441	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600041		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Asthenia; Condition Aggravated; Contraindicated Product Administered; Cough; Drug Ineffective; Fatigue; Fine Motor Skill Dysfunction; Goitre; Headache; Inflammation; Joint Swelling; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Stiffness; Nasopharyngitis; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling; Thyroid Disorder	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral	Therapy Duration: 21.0 Years	Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported
	Rosuvastatin Calcium	C			Not Reported
	Citalopram Hydrobromide	C			Not Reported
	Ketoprofen	C	Unknown		Not Reported
	Losec [Omeprazole]	C	Unknown		Not Reported
	Naprosyn [Naproxen]	C	Unknown		Not Reported
	Omeprazole	C			Not Reported
	Prednisone	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825445	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599544		8 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Arthropathy; C- Reactive Protein	Actemra			S	Unknown			Not Reported	
Increased; Deformity;	Rituximab			S	Unknown			Not Reported	
Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Injection Site Reaction; Intentional	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 1.0 Months		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			S				Not Reported	



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use Issue; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet Volume Decreased; Monocyte Count Increased;	Adalimumab	S	Unknown						Not Reported
Musculoskeletal Deformity; Off Label Use; Osteoarthritis; Pain;	Adalimumab	S	Subcutaneous						Not Reported
Physical Disability; Platelet Count Increased; Product Use Issue; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Red Cell Distribution Width Decreased; Red Cell Distribution Width Increased; Rheumatoid Arthritis; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Enbrel	S	Subcutaneous						Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 610.0 Days					Not Reported
	Enbrel	S	Subcutaneous						Not Reported
	Etanercept	S	Subcutaneous						Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 4.0 Years					Not Reported
	Humira	S	Subcutaneous						Not Reported
	Hydroxychloroquine Sulfate	S	Unknown						Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Months					Not Reported
	Infliximab	S	Intravenous (not otherwise specified)						Not Reported
	Leflunomide	S	Oral	Therapy Duration: 2.0 Months					Not Reported
	Methotrexate	S	Subcutaneous	Therapy Duration: 2.0 Months					Not Reported
	Methotrexate	S	Subcutaneous						Not Reported
	Orencia	S	Unknown						Not Reported
	Orencia	S							Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown						Not Reported
	Sulfasalazine	S	Unknown						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17825474	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020205625		58 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Electrocardiogram Repolarisation Abnormality;	Zithromax			S	Oral	2 Df, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	2 Df, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatocellular Injury; Off
Label Use; Product Use In
Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825475	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2020205699		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Tachycardia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825739	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES- 1239023		90 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg		Teva	
	Morfina (1982a)			S	Intravenous (not otherwise specified)	Sedation		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr		Not Reported	
	Furosemida			C	Oral	20 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17825755	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1236224			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Discomfort; Drug Ineffective; Drug Intolerance; Fatigue;	Prednisone			S	Unknown			Actavis	
	Adalimumab			S	Subcutaneous			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Etanercept	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil[Hydroxychloroquinesulfate]	S	Unknown	400 MI Daily;	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Oral	2 Gram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826171	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1240209		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cornea Verticillata	Hydroxychloroquine			S	Unknown	1200 Milligram Daily;		Teva	
	Hydroxychloroquine			S	Unknown	1200 Milligram Daily; 21.9 Mg/Kg/Day		Teva	
	Everolimus			C	Unknown	10 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826300	EXPEDITED (15-DAY)		OT	IT-ADVANS PHARMA-202005005429			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injury; Off Label Use; Syncope	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia	
	Azithromycine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826306	EXPEDITED (15-DAY)		OT	IT-ADVANS PHARMA-202005005461			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Off Label Use; Total Lung Capacity Decreased	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826307	EXPEDITED (15-DAY)		OT	CA-ADVANS PHARMA-202005005455			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chest Discomfort; Condition Aggravated; Drug Ineffective; Gastrointestinal Disorder; Malaise; Off Label Use; Product Use Issue; Skin Lesion; Swelling; Treatment Failure	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Concordia	
	Leflunomide			S	Unknown	Film-Coated Tablet		Not Reported	
	Methotrexate			S	Oral	20 Mg, Q2m		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Fish Oil			C		Unk		Not Reported	
	Vitamin D 2000			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826310	EXPEDITED (15-DAY)		DE, HO, OT	US-ADVANZ PHARMA-202005005511			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Ventricular Arrhythmia; Ventricular Tachycardia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Bid For 1 Day		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid For 4 Days		Concordia	
	Azithromycin			S	Unknown	500 Mg, Qd For 5 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826524	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200523250		77 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Increased; Drug Interaction	Rivaroxaban			S	Oral	15 Mg, Qd		Janssen	
	Lopinavir			S	Unknown	Unk		Not Reported	
	Ritonavir			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826528	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20200523246		82 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Increased; Drug Interaction	Rivaroxaban			S	Oral	15 Mg, Qd		Janssen	
	Lopinavir			S				Not Reported	
	Ritonavir			S				Not Reported	
	Hydroxychloroquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826917	EXPEDITED (15-DAY)		OT	NVSC2020GB139840			Male	GBR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Dactylitis; Drug Ineffective; Dry Skin; Emphysema; Hypoaesthesia; Joint Injury; Joint Swelling; Joint Swelling; Nausea; Paraesthesia; Psoriatic Arthropathy; Rash; Rheumatoid Nodule; Therapeutic Product Effect Incomplete	Cosentyx			S	Oral	300 Mg		Novartis
	Cosentyx			S	Oral	40 Mg		Novartis
	Methotrexate			S	Oral	10 Mg, (10 Mg To 15 Mg)		Not Reported
	Methotrexate			S	Oral	20 Mg		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Methotrexate			S	Oral	30 Mg		Not Reported
	Methotrexate			S	Oral	15 Mg		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	2 G, Qd		Not Reported
	Sulfasalazine			S	Unknown	4 G, Qd		Not Reported
	Sulfasalazine			S	Unknown	3 G, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	1 Ot, Tiw		Not Reported
	Humira			S	Subcutaneous	1 Unk, Q4w		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Leflunomide			C	Unknown	20 Mg		Not Reported
	Leflunomide			C	Unknown	10 Mg,		Not Reported
	Leflunomide			C	Unknown	20 Mg,		Not Reported
	Tocilizumab			C	Subcutaneous	162 Mg, Qw		Not Reported
	Abatacept			C	Subcutaneous	125 Mg,		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17826954	EXPEDITED (15-DAY)		OT	NVSC2020CA034842		57 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; C-Reactive Protein Increased;	Methotrexate			S	Unknown	Unk		Novartis
Decreased Appetite; Drug Ineffective; Dysstasia;	Sulfasalazine			S	Unknown	Unk		Not Reported
Fatigue; Gait Disturbance; General Physical Health Deterioration; Grip Strength Decreased;	Hydroxychloroquine			S	Unknown			Not Reported
Hypokalaemia; Nausea; Pain	Celebrex			C	Unknown	Unk		Not Reported
	Naproxen			C	Unknown	Unk		Not Reported
	Plaquenil			C	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	10700712	EXPEDITED (15-DAY)		DS	FR-ELI_LILLY_AND_COMP ANY-FR201412010311		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Cymbalta			S	Oral	Unk, Unknown		Eli Lilly And Co
	Plaquenil /00072602/			S	Oral	Unk, Unknown		Not Reported
	Salazopyrine			S	Oral	Unk, Unknown		Not Reported
	Tahor			S	Oral	Unk, Unknown		Not Reported
	Metoject			S	Subcutaneous	Unk, Unknown		Not Reported
	Skenan			S	Oral	Unk, Unknown		Not Reported
	Cortancyl			S	Oral	Unk, Unknown		Not Reported
	Inexium /01479302/			S	Oral	Unk, Unknown		Not Reported
	Fosamax			S	Oral	Unk, Unknown		Not Reported
	Avodart			S	Oral	Unk, Unknown		Not Reported
	Cacit Vitamine D3			S	Oral	Unk, Unknown		Not Reported
	Rivotril			S	Oral	Unk, Unknown		Not Reported
	Lexomil			S	Oral	Unk, Unknown		Not Reported
	Forlax /00754501/			S	Oral	Unk, Unknown		Not Reported
	Lasilix /00032601/			S	Oral	Unk, Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	11567356	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-1638076		8 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 153 Days		Not Reported
Antibody Test Positive;	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 6.0 Months		Not Reported
Arthralgia; Arthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Diarrhoea;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive;	Naproxen			S	Unknown			Not Reported
Hypocalcaemia;	Naproxen			S	Unknown			Not Reported
Hypokalaemia;	Naproxen			S	Unknown			Not Reported
Hypotension;	Naproxen Sodium			S	Unknown			Not Reported
Immunodeficiency; Joint Destruction; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal;	Methotrexate			S	Subcutaneous			Not Reported
Loss Of Consciousness;	Methotrexate			S	Unknown			Not Reported
Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea;	Methotrexate			S	Subcutaneous			Not Reported
Obesity; Off Label Use;	Prednisone			S	Oral	Therapy Duration: 10 Years		Not Reported
Pleural Effusion;	Prednisone			S	Oral			Not Reported
Polyarthritis; Product Use In Unapproved Indication;	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 63 Days, Therapy Duration: 3 Months		Not Reported

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Psoriasis; Pyrexia; Quality Of Life Decreased; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Underdose; Vomiting; Wheelchair User	Orencia	S	Respiratory (inhalation)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Qmo	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 3 Months Therapy Duration: 62 Days	Not Reported
	Kineret	S	Subcutaneous	Therapy Duration: 700 Days, Therapy Duration: 3 Years	Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Kineret	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 8.0 Month(S)	Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 4 Months	Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)		Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Therapy Duration: 5 Months	Not Reported
	Infliximab	S	Unknown	Therapy Duration: 62 Days	Not Reported
	Sulfasalazine	S	Oral	500 Mg Tablet	Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported
	Triamcinolone	S	Unknown		Not Reported
	Triamcinolone	S	Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Iviglob-Ex	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Iviglob-Ex	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Iviglob-Ex	S	Unknown		Not Reported
Iviglob-Ex	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hydroxychloroquine Sulfate	S	Oral		Not Reported
Abatacept	S	Intravenous (not otherwise specified)		Not Reported
Abatacept	S	Intravenous drip	Therapy Duration: 3 Months	Not Reported
Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Anakinra	S	Unknown		Not Reported
Anakinra	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Suspension Intra-Articular	Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Subcutaneous	Cyclic Therapy Duration: 4 Months	Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Adalimumab	S	Subcutaneous		Not Reported
Adalimumab	S			Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Therapy Duration: 3 Months	Not Reported
Apo-Naproxen	S	Unknown		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Naproxen	S	Oral		Not Reported
Apo-Prednisone	S	Oral		Not Reported
Triamcinolone Hexacetonide	S	Unknown		Not Reported

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		Gamastan	S	Intramuscular				Not Reported	
		Folic Acid	C					Not Reported	
		Triamcinolone Hexacetonide	C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	13059019	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-APOTEX-2016AP015792		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Apparent Death; Arthropathy; C-Reactive Protein	Apo-Leflunomide			S	Unknown	Unk		Apotex	
Abnormal; C-Reactive Protein Increased;	Apo-Leflunomide			S	Oral	Unk		Apotex	
Contraindicated Product	Leflunomide			S	Unknown	Unk		Apotex	
Administered; Death;	Leflunomide			S	Oral	Unk		Apotex	
Deep Vein Thrombosis;	Hydroxychloroquine			S	Unknown	Unk		Apotex	
Diverticulitis; Drug	Hydroxychloroquine			S	Oral	Unk		Apotex	
Hypersensitivity; Drug	Hydroxychloroquine			S				Apotex	
Ineffective; Drug	Minocycline			S	Unknown	Unk		Not Reported	
Intolerance; Feeling	Oxycodone			S	Unknown	Unk		Not Reported	
Abnormal; Haemoglobin Decreased; Herpes	Sulfasalazine			S	Unknown	Unk		Not Reported	
Zoster; Intentional Product	Sulfasalazine			S				Not Reported	
Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Sulfasalazine			S				Not Reported	
Joint Swelling; Myocardial Infarction; Off Label Use;	Actemra			S	Unknown	Unk		Not Reported	
Pain; Photosensitivity	Actemra			S				Not Reported	
Reaction; Pulmonary Embolism; Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Anakinra			S	Unknown	Unk		Not Reported	
Increased; Renal Failure;	Anakinra			S				Not Reported	
Rheumatoid Arthritis; Sepsis; Stomatitis;	Enbrel			S	Unknown	Unk		Not Reported	
Terminal State;	Enbrel			S	Subcutaneous	Unk		Not Reported	
Thrombosis; Urticaria	Gold			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Humira			S				Not Reported	
	Ilaris			S	Subcutaneous	Unk		Not Reported	
	Ilaris			S	Unknown	Unk		Not Reported	
	Ilaris			S	Intravenous (not	Unk		Not Reported	

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		otherwise specified)		
Ilaris	S			Not Reported
Methotrexate	S	Intra-arterial	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate	S			Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S			Not Reported
Plaquenil /00072602/	S	Unknown		Not Reported
Plaquenil /00072602/	S			Not Reported
Remicade	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown		Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	S	Unknown	Unk	Not Reported
Arava	S			Not Reported
Arava	S			Not Reported
Xeljanz	S	Oral	Unk, Bid	Not Reported
Xeljanz	S	Unknown	5 Mg, Q.O.Wk.	Not Reported
Rituximab	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Aurothiomalate	S	Parenteral	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Marijuana	S	Unknown	Unk	Not Reported
Cannabis Sativa	S	Unknown	Unk	Not Reported
Kineret	C	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Plaquenil /00072602/	C	Oral	Unk	Not Reported

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Prednisone	C	Unknown	Unk Unk, Qd	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported
Urelumab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	13121306	EXPEDITED (15-DAY)		OT	CA-SA-2017SA006034		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
	Arava			S	Oral	20 Mg,Qd		Sanofi
	Enbrel			S	Subcutaneous	50 Mg,Qw		Not Reported
	Sulfasalazine			S	Oral	Unk Unk,Unk		Not Reported
	Cimzia			S	Unknown	200 Mg,Qow		Not Reported
	Humira			S	Unknown	40 Mg,Qow		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	500 Mg,Unk		Not Reported
	Methotrexate Sodium			S	Oral	25 Mg,Qw		Not Reported
	Methotrexate Sodium			S	Oral	17.5 Mg,Qw		Not Reported
	Methotrexate Sodium			S	Oral	15 Mg,Qw		Not Reported
	Folinic Acid			C	Unknown	Unk Unk,Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk Unk,Unk		Not Reported
	Perindopril			C	Unknown	Unk Unk,Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk Unk,Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	14223391	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX- 2017AP021500		56 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; C- Reactive Protein Abnormal; C-Reactive	Hydroxychloroquine			S	Unknown	400 Mg, Unk		Apotex
	Hydroxychloroquine			S	Unknown	400 Unk, Unk		Apotex

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Protein Increased; Deep	Hydroxychloroquine	S	Unknown	400 G, Unk	Apotex
Vein Thrombosis;	Leflunomide	S	Unknown	Unk	Apotex
Diverticulitis; Drug	Leflunomide	S			Apotex
Hypersensitivity; Drug	Apo-Leflunomide	S	Unknown	Unk	Apotex
Ineffective; Drug	Minocycline	S	Unknown	Unk	Not Reported
Intolerance; Feeling	Oxycodone	S	Unknown	10 Mg, Unk	Not Reported
Abnormal; Haemoglobin	Anakinra	S	Unknown	Unk	Not Reported
Decreased; Herpes	Anakinra	S			Not Reported
Zoster; Interstitial Lung	Actemra	S	Unknown	Unk	Not Reported
Disease; Joint Swelling;	Actemra	S			Not Reported
Myocardial Infarction; Off	Methotrexate	S	Unknown	Unk	Not Reported
Label Use; Pain;	Methotrexate	S			Not Reported
Photosensitivity Reaction;	Enbrel	S	Subcutaneous	Unk	Not Reported
Pulmonary Embolism;	Enbrel	S			Not Reported
Pulmonary Thrombosis;	Cannabis Sativa	S	Unknown	Unk	Not Reported
Red Blood Cell	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sedimentation Rate	Remicade	S	Unknown	Unk	Not Reported
Abnormal; Red Blood Cell	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sedimentation Rate	Orencia	S	Unknown	Unk	Not Reported
Increased; Renal Failure;	Ilaris	S	Subcutaneous	Unk	Not Reported
Rheumatoid Arthritis;	Ilaris	S	Unknown	Unk	Not Reported
Sepsis; Stomatitis;	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
Terminal State;	Plaquenil /00072602/	S			Not Reported
Thrombosis; Urticaria	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	500 Mg, Unk	Not Reported

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Sulfasalazine	S			Not Reported
Gold	S	Unknown	Unk	Not Reported
Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
Lyrica	C	Oral	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Marijuana	C	Unknown	Unk	Not Reported
Orencia	C	Intravenous (not otherwise specified)	Unk	Not Reported
Oxycodone	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	7 Mg, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Xeljanz	C	Oral	5 Mg, Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Anakinra	C	Unknown	Unk	Not Reported
Rituximab W/Urelumab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	14535482	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2018CA0123			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Arthroplasty;	Kineret			S	Subcutaneous			Not Reported
Arthralgia; Arthropathy;	Kineret			S	Unknown			Not Reported
Contraindicated Product	Actemra			S	Subcutaneous			Not Reported
Administered; Deformity;	Arava			S	Oral			Not Reported
Drug Hypersensitivity;	Cimzia			S	Subcutaneous			Not Reported
Drug Ineffective; Foot	Enbrel			S	Subcutaneous			Not Reported
Deformity; Foot Operation;	Enbrel			S	Subcutaneous			Not Reported
Hepatotoxicity; Ill-Defined	Humira			S	Subcutaneous			Not Reported
Disorder; Infection; Loss	Humira			S	Subcutaneous			Not Reported
Of Consciousness;	Humira			S	Unknown			Not Reported
Malaise; Mobility								
Decreased;								
Musculoskeletal Disorder;								
Musculoskeletal Pain;								
Nausea; Neck Pain;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nodule; Off Label Use;	Hydroxychloroquine	S	Oral		Not Reported
Pain; Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown		Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine	S	Unknown		Not Reported
Syncope; Therapeutic	Orencia	S	Intravenous (not otherwise specified)		Not Reported
Product Effect Decreased;	Orencia	S	Unknown		Not Reported
Therapeutic Product Effect Incomplete	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution Intravenous	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution Subcutaneous	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Gold	S			Not Reported
	Plaquenil	S			Not Reported
	Plaquenil	S	Oral		Not Reported
	Apo-Hydroxyquine	S			Not Reported
	Methotrexate	S		Dose: 17.5 Mg	Not Reported
	Methotrexate	S			Not Reported
	Actonel	S			Not Reported
	Apo-Leflunomide	S			Not Reported
	Certolizumab Pegol	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported
	Prednisone	C	Intravenous (not otherwise specified)		Not Reported
	Adalimumab	C	Unknown		Not Reported
	Adalimumab	C			Not Reported

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Xeljanz	C	Unknown		Not Reported
Methotrexate	C		Dosage Form: Not Specified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	14535486	EXPEDITED (15-DAY)		DE, HO, LT, OT	CA-BIOVITRUM-2018CA0124		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death;	Anakinra			S	Unknown			Not Reported
Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Anakinra			S	Unknown			Not Reported
Contraindicated Product Administered; Deep Vein Thrombosis; Diverticulitis;	Actemra			S	Unknown			Not Reported
Drug Hypersensitivity;	Actemra			S				Not Reported
Drug Ineffective; Drug Intolerance; Feeling Abnormal; Haemoglobin Decreased; Herpes Zoster; Intentional Product Use Issue; Interstitial Lung Disease; Intestinal Sepsis;	Apo Sulfasalazine Tab 500mg			S				Not Reported
Joint Arthroplasty; Joint Swelling; Knee Arthroplasty; Myocardial Infarction; Off Label Use;	Apo Sulfasalazine Tab 500mg			S				Not Reported
Pain; Photosensitivity Reaction; Product Use In Unapproved Indication;	Apo-Leflunomide			S	Oral			Not Reported
Pulmonary Embolism;	Apo-Leflunomide			S	Unknown			Not Reported
Pulmonary Thrombosis; Red Blood Cell Sedimentation Rate	Enbrel			S	Subcutaneous			Not Reported
Increased; Renal Failure; Rheumatoid Arthritis;	Enbrel			S				Not Reported
Sepsis; Stent Placement; Stomatitis; Terminal State;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Thrombosis; Urticaria	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S		Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S		Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S		Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Subcutaneous	Not Reported
	Ilaris Single-Use Vial	S	Unknown	Not Reported
	Ilaris Single-Use Vial	S	Intravenous (not otherwise specified)	Not Reported
	Gold	S	Unknown	Not Reported
	Gold	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S		Not Reported
	Plaquenil	S	Unknown	Not Reported
	Plaquenil	S		Not Reported
	Arava	S	Unknown	Not Reported
	Arava	S		Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sodium Aurothiomalate	S		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cannabis Sativa	S		Not Reported
Cannabis Sativa	S		Not Reported
Oxycodone	S		Not Reported
Minocycline Hydrochloride	S		Not Reported
Rituximab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Minocycline	S	Unknown	Not Reported
Oxyquinoline Sulfate	S		Not Reported
Xeljanz	S	Oral	Not Reported
Sulfasalazine	S		Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Hydroxychloroquine Sulfate	S		Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Marijuana	S		Not Reported
Lyrica	C		Not Reported
Urelumab	C	Unknown	Not Reported
Kineret	C		Not Reported
Lyrica	C	Oral	Not Reported
Plaquenil	C		Not Reported
Prednisone	C	Unknown	Not Reported
Rituximab	C		Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C		Not Reported
Xeljanz	C	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported
Kineret	C		Not Reported
Lyrica	C	Oral	Not Reported
Plaquenil	C	Oral	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	15428288	EXPEDITED (15-DAY)		OT	CA-ROCHE-2189244		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory Impairment; Mobility Decreased; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	15543164	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016253265		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Hepatic Enzyme Increased; Joint Swelling; Off Label Use; Pneumonia; Prescribed Underdose; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Subcutaneous	Unk		Unknown
	Enbrel			S	Unknown	Unk		Unknown
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Actemra			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk (Powder And Solvent For Solution For Injection/Infusion)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Rituxan	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown	Unk	Not Reported
Plaquenil	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Apo-Azathioprine	S	Unknown	Unk	Not Reported
Azathioprine	S	Unknown	Unk	Not Reported
Hydroxychloroquine	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S		Unk	Not Reported
Prednisone	C	Unknown	5 Mg, 1x/Day (Every 24 Hours)	Not Reported
Prednisone	C	Unknown	10 Mg, 2x/Day	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	15834762	EXPEDITED (15-DAY)		OT	CA-ROCHE-2245786		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Actemra			S	Unknown			Not Reported
Drug Ineffective; Herpes Zoster; Peripheral	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling; Pneumonia Viral	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified) Powder For Solution Intravenous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	15932350	EXPEDITED (15-DAY)		HO, OT	US-SA-2019SA030298		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Atrioventricular Block; Coronary Artery Occlusion; Herpes Zoster; Mobility Decreased; Osteoporosis; Spinal Fracture	Ambien			S	Unknown	Unk Unk, Unk		Sanofi
	Nifedipine			S	Unknown	Unk, Unk		Not Reported
	Metoclopramide Hydrochloride			S	Unknown	Unk, Unk		Not Reported
	Trazodone Hydrochloride			S		Unk, Unk		Not Reported
	Loperamide			S	Unknown	Unk, Unk		Not Reported
	Gabapentin			S	Unknown	Unk, Unk		Not Reported
	Esomeprazole Magnesium			S	Unknown	Unk, Unk		Not Reported
	Isosorbide Mononitrate			S				Not Reported
	Plavix			S	Unknown			Sanofi
	Famotidine			S				Not Reported
	Rosuvastatin Calcium			S				Not Reported
	Potassium			S				Not Reported
	Glyceryl Trinitrate			S				Sanofi
	Venlafaxine Hydrochloride			S	Unknown			Not Reported
	Doxycycline			S				Not Reported
	Trandolapril			S				Not Reported
	Prednisone			S				Not Reported
	Hydroxychloroquine			S				Sanofi
	Flomax			S				Sanofi
	Furosemide			S				Sanofi
	Victoza			S				Not Reported
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported

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Humira			S	Subcutaneous	40 Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	16691241	EXPEDITED (15-DAY)		OT	CA-SA-2019SA208333		50 YR	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer Stage Iii; Depression; Diarrhoea; Sleep Disorder; Treatment Noncompliance	Arava			S		Unk		Sanofi	
	Hydroxychloroquine			S		Unk		Sanofi	
	Methotrexate			S	Subcutaneous	Unk		Not Reported	
	Sulfasalazine			S		Unk		Not Reported	
	Enbrel			S		Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Orencia			S		Unk		Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	16720233	EXPEDITED (15-DAY)		OT	CA-SA-2019SA217087		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Affect Lability; Anxiety; Blood Pressure Fluctuation; Depression; Drug Ineffective; Finger Deformity; Foot Operation; Headache; Hyperhidrosis; Joint Swelling; Nausea; Night Sweats; Osteoarthritis; Palpitations; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Oral	20 Mg, Qd		Sanofi	
	Plaquenil			S	Unknown	Unk		Sanofi	
	Sulfasalazine			S	Oral	Unk		Not Reported	
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported	
	Methotrexate			S	Oral	17.5 Mg, Qw		Not Reported	
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Qow		Not Reported	
	Orencia			S	Intravenous (not	500 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Cimzia	S	Subcutaneous	200 Mg, Qow	Not Reported
Leucovorin [Calcium Folate]	C	Unknown	Unk	Not Reported
Ergocalciferol	C		Unk	Not Reported
Coversyl [Perindopril Arginine]	C	Unknown	Unk	Not Reported
Vitamin D [Ergocalciferol]	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	16774890	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-219753			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Oedema Peripheral; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Therapy Cessation; Visual Impairment	Ramipril			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Ranbaxy
	Ramipril			S	Unknown	5 Milligram		Ranbaxy
	Pregabalin			S	Unknown	100 Milligram, Tid		Sun
	Omeprazole			S	Oral	1 Df, 2x/Day (1 - 0 - 1); 1 Number Of Units In The Interval: 12 Definition Of The Interval: Hour		Astrazeneca
	Omeprazole			S	Unknown	20 Mg, Bid		Astrazeneca
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Quensyl			S	Unknown	1 Df, Bid (1 - 0 - 1)		Not Reported
	Quensyl			S	Unknown	20 Mg Bid		Not Reported
	Eliquis			S	Unknown	2.5 Milligram, Bid		Not Reported
	Spasmolyt			S	Unknown	1 Df, Qd		Not Reported

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Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	15 Milligram	Not Reported
Spasmolyt	S	Unknown		Not Reported
Volibris	S	Oral	1 Dosage Form, Qd	Not Reported
Ambrisentan	S	Unknown	1 Dosage Form, Qd	Not Reported
Lyrica	S	Unknown	300 Milligram, Daily	Not Reported
Lyrica	S		1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))	Not Reported
Eliquis	S	Unknown	2 Dosage Form, Daily	Not Reported
Apixaban	S	Unknown	2 Df, Qd	Not Reported
Apixaban	S	Unknown	2.5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	16884537	EXPEDITED (15-DAY)		OT	CA-ROCHE-2418235		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Endocervical			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

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	Neoral	S	Subcutaneous	Not Reported
	Neoral	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17081625	NON-EXPEDITED			US-UCBSA-2018055688		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Cimzia			S		Unk		Not Reported	
	Vitamin D			C				Not Reported	
	Hydroxychloroquine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17302264	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013796			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Arava			S	Unknown	Unk		Sanofi	
Alopecia; Contraindicated	Diclofenac Sodium			S	Unknown	Unk		Not Reported	
Product Administered;	Folic Acid			S	Unknown	Unk		Not Reported	
Glossodynia; Hip	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
Arthroplasty; Knee	Hydroxychloroquine			S	Unknown	Unk		Sanofi	
Arthroplasty; Maternal	Methotrexate			S	Unknown	Unk		Not Reported	
Exposure During	Alendronate Sodium			S	Unknown	Unk		Not Reported	
Pregnancy; Pain;	Plaquenil			S	Unknown	Unk		Sanofi	
Pemphigus; Product Use									
Issue; Rheumatoid									
Arthritis; Systemic Lupus									
Erythematosis									

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	Prednisone	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17308071	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013870			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Arava			S	Unknown			Sanofi
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			S	Oral	25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	Unk, Qw		Not Reported
	Myochrysine			S	Intramuscular	25 Mg, Qw		Not Reported
	Enbrel			S	Unknown	50 Mg, Qw		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17315938	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013861		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Breast Cancer Stage Iii; Depression; Diarrhoea; Off Label Use; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava	S	Unknown	Unk	Sanofi
	Hydroxychloroquine	S	Unknown		Sanofi
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Sanofi
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Gold	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17333490	EXPEDITED (15-DAY)		HO	CA-ROCHE-2529931		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Headache; Hepatic Cyst; Hepatic Haematoma; Hepatitis B Core Antibody Positive; Joint Swelling; Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Neutropenia; Pulmonary Mass; Pyrexia; Renal Cyst	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Oral	Not Reported
Zostavax	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17376781	EXPEDITED (15-DAY)	OT		CA-ROCHE-2531725			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Headache; Loss Of Personal Independence In Daily Activities; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Tofacitinib			S	Unknown			Not Reported
	Tofacitinib Citrate			S	Unknown			Not Reported
Leflunomide			C				Not Reported	
Sulfasalazine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17416777	EXPEDITED (15-DAY)	OT		US-SA-2020SA038806		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Pain In Extremity; Pleural Effusion; Rheumatoid Arthritis; Rheumatoid Arthritis; Skin Infection	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Humira			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17433130	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA0820		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Fatigue; Infiltration Anaesthesia; Joint Arthroplasty; Knee Arthroplasty; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Treatment Failure; Vasculitic Rash	Anakinra			S	Subcutaneous			Not Reported	
	Anakinra			S				Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg (Previously)		Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Apo-Leflunomide			S				Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous	Cyclical		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral	12.5 Mg Daily		Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Oral		Not Reported
Methotrexate	S	Subcutaneous	12.5 Mg Daily	Not Reported
Methotrexate	S	Unknown		Not Reported
Neoral	S	Oral		Not Reported
Neoral	S	Subcutaneous		Not Reported
Remicade	S			Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	C	Oral		Not Reported
Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17450107	EXPEDITED (15-DAY)		DS, HO, LT, OT	CA-BIOVITRUM-2020CA0815		3 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Kineret			S	Subcutaneous			Not Reported
Antibody Test Positive;	Kineret			S	Subcutaneous			Not Reported
Arthralgia; Arthritis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; Body Height Below Normal; Bone Density Decreased; Bone Density Increased; C-Reactive Protein Increased; Condition Aggravated;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Contraindicated Product Administered; Diarrhoea;	Actemra			S				Not Reported
Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Drug Specific Antibody Present;	Adalimumab			S	Subcutaneous			Not Reported
Gastroenteritis Viral; Human Anti-Human Antibody Test; Human	Adalimumab			S				Not Reported
	Apo-Naproxen			S				Not Reported
	Apo-Naproxen			S				Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg 1x1 Daily		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous	12.5 Mg 1x1 Daily		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Antichimeric Antibody	Enbrel	S	Unknown	1.5 Mg 1x1 Daily	Not Reported
Positive; Hypocalcaemia;	Humira	S	Subcutaneous		Not Reported
Hypokalaemia;	Hydroxychloroquine Sulfate	S	Oral		Not Reported
Hypotension;	Hydroxychloroquine Sulfate	S	Oral		Not Reported
Immunodeficiency;	Immunoglobulins	S	Intravenous (not		Not Reported
Impaired Quality Of Life;	[Immunoglobulin Human Normal]		otherwise specified)		
Intentional Product Use	Immunoglobulins	S	Intravenous (not		Not Reported
Issue; Joint Destruction;	[Immunoglobulin Human Normal]		otherwise specified)		
Joint Effusion; Joint Injury;	Immunoglobulins	S	Intravenous (not		Not Reported
Juvenile Idiopathic	[Immunoglobulin Human Normal]		otherwise specified)		
Arthritis; Liver Function	Immunoglobulins	S	Intravenous (not		Not Reported
Test Abnormal; Loss Of	[Immunoglobulin Human Normal]		otherwise specified)		
Consciousness; Loss Of	Infliximab	S	Intravenous (not		Not Reported
Personal Independence In			otherwise specified)		
Daily Activities; Mobility	Infliximab	S	Intravenous (not		Not Reported
Decreased; Nausea;			otherwise specified)		
Obesity; Off Label Use;	Infliximab	S	Intravenous (not		Not Reported
Pleural Effusion;			otherwise specified)		
Polyarthritis; Prescribed	Infliximab	S	Intravenous (not		Not Reported
Underdose; Product Use			otherwise specified)		
In Unapproved Indication;	Infliximab	S	Intravenous (not		Not Reported
Psoriasis; Pyrexia; Quality			otherwise specified)		
Of Life Decreased; Red	Methotrexate	S	Subcutaneous		Not Reported
Blood Cell Sedimentation	Methotrexate	S	Subcutaneous		Not Reported
Rate Abnormal; Red Blood	Methotrexate	S	Subcutaneous		Not Reported
Cell Sedimentation Rate	Methotrexate	S	Subcutaneous		Not Reported
Increased; Rheumatoid	Methotrexate	S	Subcutaneous		Not Reported
Arthritis; Septic Shock;	Methotrexate	S	Unknown		Not Reported
Synovitis; Therapeutic	Naproxen Sodium	S	Unknown		Not Reported
Product Effect Decreased;					
Therapy Non-Responder;	Naproxen Sodium	S			Not Reported
Underdose; Vomiting;	Orencia	S	Intravenous (not		Not Reported
Wheelchair User			otherwise specified)		
	Orencia	S	Intravenous (not		Not Reported
			otherwise specified)		
	Orencia	S	Intravenous (not		Not Reported
			otherwise specified)		
	Prednisone	S	Oral	1.3 Mg 2x1 Daily	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S		Not Reported
Triamcinolone	S	Subcutaneous	Not Reported
Triamcinolone	S	Intra-articular	Not Reported
Triamcinolone	S	Unknown	Not Reported
Triamcinolone	S		Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S	Intravenous (not otherwise specified)	Not Reported
Gammagard Liquid Also Know As Immune Globulin (Human)	S		Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Apo Prednisone	S	Oral	Not Reported
Apo Prednisone	S	Oral	Not Reported
Apo Prednisone	S	Oral	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
Etanercept	S	Subcutaneous 12.5 Mg 1x1 Week	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Gamastan	S	Intramuscular	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Unknown	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
Immune Globulin (Immunoglobulins Nos)	S	Unknown	Not Reported
Immune Globulin	S	Intravenous (not	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

(Immunoglobulins Nos)		otherwise specified)	
Naproxen	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Triamcinolone Hexacetonide	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Not Reported
Triamcinolone Acetonide	C	Unknown	Not Reported
Triamcinolone Acetonide	C	Oral	Not Reported
Triamcinolone Acetonide	C	Intra-articular	Not Reported
Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17580229	EXPEDITED (15-DAY)		DS, OT	CA-BIOVITRUM-2020CA1335		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Arthroplasty; Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Foot Operation; Hand Deformity; Hypertension; Ill-Defined Disorder; Infection; Intentional Product Use Issue; Limb Discomfort; Loss Of Consciousness; Malaise; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S	Oral			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

**FDA Adverse Event Reporting System
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Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis	Gold	S	Unknown	Not Reported
	Gold	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Dose: 17.5 Mg Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Oral	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Xeljanz	S	Oral	Not Reported
	Risedronate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	S	Unknown		Not Reported
	Risedronate	C	Unknown		Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Hydroxychloroquine Sulfate	C			Not Reported
	Xeljanz	C	Oral		Not Reported
	Methotrexate	C	Unknown	Dose: 17.5 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17591358	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009095		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Ineffective	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Leflunomide			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Supeudol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17633457	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM-2020CA1653		45 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue;	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia Single-Use Prefilled			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Syringe Cimzia Single-Use Prefilled Syringe Enbrel Enbrel Gold Humira Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Hydroxychloroquine Sulfate Leflunomide Leflunomide Methotrexate Methotrexate Mycophenolate Mofetil Orencia Orencia Prednisone Remicade Remicade Rituxan Simponi Simponi Sodium Aurothiomalate Cellcept Plaquenil Sulfasalazine Celebrex Xeljanz	S S S S S S S S S S S S S S S S S S S S S S S S S S S C	 Subcutaneous Unknown Unknown Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Intravenous (not otherwise specified) Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Oral	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira	C	Subcutaneous	Not Reported
	Celebrex	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17715753	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR- APL-2020-020591			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Discomfort; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17721718	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA- 202004004071			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea;	Hydroxychloroquine			S	Unknown	Unk		Concordia
Haematochezia; Injection	Hydroxychloroquine			S				Concordia
Site Erythema; Injection	Dupilumab			S	Subcutaneous	600 Mg Once		Not Reported
Site Pain; Injection Site	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
Rash; Musculoskeletal	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
Pain; Osteoarthritis;	Dupilumab			S	Subcutaneous	300 Mg Qow		Not Reported
Product Storage Error;	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported
Product Use Issue								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17753736	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP010526			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Drug Resistance; Ocular Toxicity; Pain; Rheumatoid Arthritis; Swelling	Leflunomide	S	Oral	10 Mg, Unk	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Oral	400 Mg, Qd	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17754876	EXPEDITED (15-DAY)		DE, OT	BE-SA-2020SA115641		83 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Off Label Use; Product Use Issue; Respiratory Failure; Wrong Technique In Product Usage Process	Kevzara			S	Intravenous (not otherwise specified)	400 Mg		Sanofi
	Kevzara			S				Sanofi
	Hydroxychloroquine Sulfate			S	Oral	2 Df, Bid		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	1 Df, Bid		Sanofi
	Plaquenil			S	Oral	2 Df, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Plaquenil			S	Oral	1 Df, Bid		Sanofi
	Azithromycin			C	Oral	250 Mg, Qd		Not Reported
	Sodium Chloride			C	Subcutaneous	Unk		Not Reported
	Sodium Chloride			C				Not Reported
	Cefuroxime			C		1 Df, Tid		Not Reported
	Clopidogrel Sandoz [Clopidogrel]			C		75 Mg		Not Reported
	Inderal			C		40 Mg, Qd		Not Reported
	Perindopril			C		4 Mg, Qd		Not Reported
	Morphine Hydrochloride			C	Intravenous bolus	2 Mg, Q4h		Not Reported
	Sodium Chloride			C	Intravenous bolus	2 Mg, Q4h		Not Reported
	Dafalgan Forte			C	Oral	Unk Unk, Q6h		Not Reported
	Dafalgan Forte			C				Not Reported
	Dafalgan Forte			C				Not Reported

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Paracetamol B Braun	C	Intravenous drip	3 Df	Not Reported
Clexane	C	Subcutaneous	60 Mg, Bid	Not Reported
Simvastatine	C	Oral	1 Df	Not Reported
Pantomed [Pantoprazole Sodium Sesquihydrate]	C	Oral	1 Df, Qd	Not Reported
Pantomed [Pantoprazole Sodium Sesquihydrate]	C	Intravenous bolus	1 Df, Bid	Not Reported
Basaglar	C	Subcutaneous	22 U, Qd	Not Reported
Basaglar	C	Subcutaneous	18 U, Bid	Not Reported
Novorapid	C	Subcutaneous	Unk	Not Reported
Haldol [Haloperidol]	C	Oral	5 Gtt Drops, Qd	Not Reported
Midazolam B Braun	C	Intravenous bolus	5 Mg	Not Reported
Sodium Chloride	C	Intravenous bolus	Unk	Not Reported
Remergon	C	Oral	1 Df, Qd	Not Reported
Tamsulosin	C	Oral	1 Df, Qd	Not Reported
Ciproxin [Ciprofloxacin Hydrochloride]	C		2 Df, Qd	Not Reported
Cymbalta	C	Oral	1 Df	Not Reported
Coversyl [Perindopril Erbumine]	C	Oral	1 Df	Not Reported
Asaflow	C	Oral	1 Df	Not Reported
Contramal	C	Oral	1 Df	Not Reported
Sildenafil Sandoz	C	Oral	0.5 Df	Not Reported
Zocor	C	Oral	1 Df	Not Reported
Mirtazapine	C		15 Mg	Not Reported
Lantus	C		22 lu	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17758914	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748937		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased;	Actemra			S	Intravenous (not	Therapy Duration: 3		Not Reported

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Contraindicated Product			otherwise specified)	Months	
Administered; Drug	Actemra	S	Intravenous (not	Therapy Duration: 2	Not Reported
Ineffective; Joint Swelling;			otherwise specified)	Months	
Rheumatoid Arthritis;	Actemra	S	Intravenous (not	Therapy Duration: 3	Not Reported
Treatment Failure			otherwise specified)	Months	
	Methotrexate Sodium	S	Oral		Not Reported
	Methotrexate Sodium	S	Oral	Therapy Duration: 16.0	Not Reported
				Year(S)	
	Methotrexate Sodium	S	Subcutaneous	Therapy Duration: 16.0	Not Reported
				Year(S)	
	Neoral	S	Subcutaneous	Therapy Duration 15	Not Reported
				Years	
	Neoral	S	Oral		Not Reported
	Neoral	S	Subcutaneous	Therapy Duration: 16.0	Not Reported
				Year(S)	
	Plaquenil [Hydroxychloroquine	S	Subcutaneous	Therapy Duration: 15	Not Reported
	Sulfate]			Years	
	Plaquenil [Hydroxychloroquine	S	Oral		Not Reported
	Sulfate]				
	Plaquenil [Hydroxychloroquine	S	Oral	Therapy Duration: 16.0	Not Reported
	Sulfate]			Year(S)	
	Remicade	S	Intravenous (not	Therapy Duration: 11	Not Reported
			otherwise specified)	Years	
	Cyclosporine	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 3.0	Not Reported
				Month(S)	
	Orencia	S	Subcutaneous	Therapy Duration: 10.0	Not Reported
				Months	
	Orencia	S	Subcutaneous	Therapy Duration: 3.0	Not Reported
				Month(S)	
	Leflunomide	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826236	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247563		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Hydroxychloroquine			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826324	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607145		34 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported	
	Apremilast			S	Unknown			Not Reported	
	Cimzia			S	Unknown	Single-Use Prefilled Syringe		Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cosentyx			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Otezla			S	Oral			Not Reported	
	Otezla			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Benzylpenicillin			C	Unknown			Not Reported	
	Infliximab			C	Unknown			Not Reported	

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27-May-2020	17826483	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604951			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826546	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607098		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Cartilage Atrophy; Drug Ineffective; Joint Swelling; Nausea; Nephrotic Syndrome; Periorbital Oedema; Renal Disorder; Skin Erosion; Therapeutic Product Effect Decreased;	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Wrist Deformity	Rituximab	S	Unknown	Not Reported
	Leflunomide	C	Oral	Not Reported
	Naproxen	C	Unknown	Not Reported
	Sulfasalazine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826617	EXPEDITED (15-DAY)		OT	JP-ADVANS PHARMA-202005005469			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Hypokinesia	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Daily Dosage: 200mg/400mg		Concordia	
	Fluconazole			S	Unknown	Unk		Not Reported	
	Dobutamine			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826772	EXPEDITED (15-DAY)		DE, OT	US-ADVANS PHARMA-202005005590			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Multiple Organ Dysfunction Syndrome; Off Label Use; Renal Failure	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg, Bid (Day 0)		Concordia	
	Hydroxychloroquine [Hydroxychloroquine Sulfate]			S		400 Mg, Bid (Days 1-4)		Concordia	
	Tacrolimus			S	Unknown	6 Mg, Bid		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg		Not Reported	
	Lopinavir/Ritonavir			S		400 Mg, Bid (For 5 Days)		Not Reported	
	Micafungin			S		100 Mg, Qd		Not Reported	
	Sulfamethoxazole-Trimethoprim-Ds			S		Unk		Not Reported	
	Heparin			S				Not Reported	
	Tobramycin			S		Unk		Not Reported	
	Mycophenolic Acid			S		360 Mg, Bid		Not Reported	

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Linezolid	S	Unk	Not Reported
Cefepime	C	Unk	Not Reported
Vancomycin	C		Not Reported
Oseltamavir	C	Unk	Not Reported
Ivig	C	Intravenous (not otherwise specified) 10 G	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826775	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202005005592			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphopenia; Toxicity To Various Agents	Hydroxychloroquine			S		Unk		Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826838	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202005005793			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoxia; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Cyclosporine			C		100 Mg, Bid (Goal Trough 75-100 Ng/ML)		Not Reported	
	Mycophenolate Mofetil			C		250 Mg, Bid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17826909	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202005005611			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown	Unk, Coated Tablet		Concordia	
	Hydroxychloroquine			S				Concordia	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827028	EXPEDITED (15-DAY)		OT	CA-ROCHE-2600632			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Fatigue; Glossodynia; Hand Deformity; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Fosamax			S	Oral			Not Reported
	Fosamax			S				Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827186	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605529		36 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Stiffness; Joint Swelling; Nausea; Oral Discomfort; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown	5.0 Months		Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Kevzara			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Mefenamic Acid			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Simponi			S	Unknown	6.0 Months		Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Folic Acid			C				Not Reported	
	Metformin			C	Unknown			Not Reported	
	Rabeprazole Sodium			C	Oral			Not Reported	
	Synthroid			C				Not Reported	

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27-May-2020	17827283	EXPEDITED (15-DAY)		HO, OT	RU-SA-2020SA135428		28 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Iron Deficiency Anaemia; Placental Disorder; Placental Insufficiency; Pre-Eclampsia	Clexane			S		Unk Unk, Bid		Sanofi	
	Prednisone			S		Unk Unk, Q3h		Not Reported	
	Methylprednisolone			S		Unk Unk, Q12h		Not Reported	
	Plaquenil			S		Unk Unk, Bid		Sanofi	
	Nifedipine			S		90 Mg, Qd		Not Reported	
	Methyldopa			S		Unk Unk, Q6h		Not Reported	
	Omeprazole			S		Unk Unk, Bid		Not Reported	
	Levothyroxine Sodium			S				Not Reported	
	Progesterone			S		400 Unk, Qd		Not Reported	
	Azathioprine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827300	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602408		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Adverse Drug Reaction; Alanine Aminotransferase Increased; Alopecia; Anxiety; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Depression; Diarrhoea; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue; Headache; Inflammation; Joint Injury; Liver Disorder;	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	

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Malaise; Nausea; Off	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Label Use; Pain; Red	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Blood Cell Sedimentation	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rate Increased;	Infliximab	S	Unknown		Not Reported
Rheumatoid Arthritis;	Leflunomide	S	Unknown		Not Reported
Synovitis; Treatment	Methotrexate	S	Unknown	Therapy Duration: 20.0 Years	Not Reported
Failure	Methotrexate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 3.0 Months	Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 12.0 Months	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral	Therapy Duration: 2.0 Months	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Acetaminophen	C			Not Reported
	Cetirizine Hydrochloride	C			Not Reported
	Cortisone	C			Not Reported
	Desoximetasone	C			Not Reported
	Dexamethasone	C			Not Reported
	Gabapentin	C			Not Reported
	Paracetamol	C			Not Reported
	Reactine [Cetirizine Hydrochloride]	C			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827314	EXPEDITED (15-DAY)		OT	BN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247483		60 YR	Female	BRN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block Right; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Unknown	Unk		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827322	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131185			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Non- Hodgkin'S Lymphoma	Arava			S	Unknown			Sanofi	
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi	
	Methotrexate			S	Subcutaneous	250 Mg		Not Reported	
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported	
	Sulfasalazine			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	100 Mg		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported	
	Hydroxychloroquine			C				Not Reported	
	Leflunomide			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827324	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131118			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Breast Cancer; Hepatic Cirrhosis; Injection Site Reaction; Neuropathy Peripheral; Nonalcoholic Fatty Liver Disease; Pruritus; Treatment Failure	Leflunomide	S	Oral		Sanofi
	Methotrexate	S	Subcutaneous	25 Mg, 1 Every 1 Week	Not Reported
	Sodium Aurothiomalate	S	Parenteral		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral	400 Mg, 1 Every 1 Day	Sanofi
	Sarilumab	S	Subcutaneous	20 Mg, 1 Every 2 Weeks	Sanofi
	Azathioprine	S	Unknown		Not Reported
	Ciclosporin	S	Unknown		Not Reported
	Actemra	S	Subcutaneous	162 Mg, 1 Every 1 Week	Not Reported
	Enbrel	S	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Esomeprazole	C	Unknown		Not Reported
	Magnesium	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827325	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131172			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Non-Hodgkin'S Lymphoma	Arava			S		Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	100 Mg		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported

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Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Amoxil [Amoxicillin]	C	Unknown	Unk	Not Reported
Amoxicillin Trihydrate;Clavulanate Potassium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827327	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131066		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo- Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Leflunomide Leflunomide Hydroxychloroquine Methotrexate Meloxicam Actemra Gold Humira Orencia Depo-Medrol Diclofenac Hydroxychloroquine Sulfate Pantoprazole Magnesium Prednisone Xeljanz			S S S S S S S S S C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Oral	Unk Unk Unk 20 Mg, Qw Unk 160 Mg, Qw Unk Unk 80 Mg, Qd Unk Unk Unk Unk 5 Mg, (2 Every 1 Day)		Sanofi Sanofi Sanofi Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827361	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131242			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Musculoskeletal Stiffness; Pain In Extremity; Rheumatoid Arthritis	Arava			S	Oral	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, Bid		Sanofi
	Methotrexate			S	Oral	15 Mg, Qw		Not Reported
	Levothyroxine Sodium			S	Oral	175 Mg, Qd		Not Reported
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827363	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131316		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Leflunomide			S	Unknown	20 Mg		Sanofi
	Celecoxib			S	Unknown	200 Mg		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk Unk, Qw		Not Reported
	Methotrexate			S	Oral	25 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	8 Mg		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Subcutaneous	125 Mg, Qw		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	200 Mg, Bid		Not Reported
	Hydroxychloroquine Sulfate			C	Unknown	200 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827364	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131199			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Lung Disorder; Respiratory Disorder	Leflunomide	S	Unknown	Unk	Sanofi
	Methotrexate	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Sanofi
	Remicade	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827450	EXPEDITED (15-DAY)		OT	CA-SA-2020SA131500		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Stage Iii; Contraindicated Product Administered; Depression; Diarrhoea; Rheumatoid Arthritis; Sleep Disorder; Treatment Noncompliance	Arava			S	Unknown	Unk		Sanofi
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827568	EXPEDITED (15-DAY)		OT	ES-SA-2020SA135372		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Hepatitis; Off Label Use	Hydroxychloroquine	S	Oral	400 Mg Day	Sanofi
	Hydroxychloroquine	S			Sanofi
	Azithromycin	S	Oral	500 Mg Day	Not Reported
	Enoxaparin Sodium	S	Subcutaneous	60 Mg	Sanofi
	Roactemra	S	Intravenous (not otherwise specified)	600 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827635	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247555		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Multiple Organ Dysfunction Syndrome	Hydroxychloroquine			S	Unknown	Unk		Sun	
	Hydroxychloroquine			S				Sun	
	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported	
	Lopinavir/Ritonavir			S				Not Reported	
	Tocilizumab			S	Unknown	Unk		Not Reported	
	Tocilizumab			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827643	EXPEDITED (15-DAY)		HO, OT	CA-BIOVITRUM- 2020CA2713		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Event; Angiopathy; Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Infection; Pneumonia; Post Procedural Contusion; Rheumatoid Arthritis; Venous Injury; Visual Impairment	Kineret			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17827768	NON-EXPEDITED			NVSC2020US143358			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Hydroxychloroquine			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828357	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1051051		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported	
	Hydroxyzine Hydrochloride			S	Intravenous (not otherwise specified)	25 Milligram, Q6h		Mylan	
	Plaquenil /00072603/			S	Oral	200 Milligram, Bid, 12 Hrs		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828429	EXPEDITED (15-DAY)		LT	ES-ACCORD-183232		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Intrusive Thoughts; Off Label Use; Suicide Attempt	Hydroxychloroquine			S	Oral	200 Mg Every 12 Hours		Not Reported	
	Levofloxacin			C	Unknown			Not Reported	
	Cortic			C	Intravenous bolus	Bolus Corticosteroids Iv		Not Reported	
	Septrin			C	Unknown			Not Reported	
	Kaletra			C	Oral			Not Reported	
	Acetylcysteine			C	Unknown			Not Reported	
	Ciclosporin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828519	NON-EXPEDITED			US-PFIZER INC-2020207672			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Nodal Osteoarthritis; Peripheral Swelling	Methotrexate Sodium			S		Unk		Pfizer
	Leflunomide			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Meloxicam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828576	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605551			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Pulmonary Toxicity	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828583	EXPEDITED (15-DAY)		LT	CA-ROCHE-2606927			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Meningitis; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Visual Impairment	Actemra			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Indometacin			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

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	Sulfasalazine		S	Unknown				Not Reported	
	Folic Acid		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828703	EXPEDITED (15-DAY)		OT	MX-ADVANSZ PHARMA-202005005364			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arterial Occlusive Disease; Off Label Use; Pollakiuria; Prostatic Disorder; Tooth Loss	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk,Coated Tablet		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601838		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Actemra			S	Unknown			Not Reported	
Alanine Aminotransferase Increased; Alopecia;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Anxiety; Arthralgia; Aspartate	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Aminotransferase Increased; Asthenia;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Depression; Drug Dependence; Drug Ineffective; Drug Intolerance; Drug Use Disorder; Fall; Fatigue;	Apo-Prednisone			S	Unknown			Not Reported	
Headache; Inflammation;	Enbrel			S	Subcutaneous			Not Reported	
Joint Injury; Liver Disorder;	Enbrel			S	Unknown			Not Reported	
Malaise; Nausea; Off Label Use; Pain; Red	Humira			S	Subcutaneous			Not Reported	
Blood Cell Sedimentation Rate Increased; Synovitis; Treatment Failure	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Oral			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Cetirizine Hydrochloride	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17828930	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605564		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Burning Sensation; Drug Ineffective; Inflammation; Joint Stiffness; Joint Swelling; Nausea; Off Label Use; Oral Discomfort; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Kevzara			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rabeprazole Sodium	S	Oral	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Tofacitinib	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829374	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-247397		51 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Porphyria	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829520	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604568		14 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clear Cell Renal Cell Carcinoma; Hair Follicle Tumour Benign; Lymphoproliferative Disorder; Off Label Use; Product Use In Unapproved Indication	Nutropin			S	Subcutaneous			Not Reported	
	Alendronate Sodium			S	Unknown			Not Reported	
	Amlodipine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Azathioprine			S				Not Reported	
	Azathioprine			S				Not Reported	
	Calcium Carbonate			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Ciclosporin			S				Not Reported	
	Cyclophosphamide			S	Unknown			Not Reported	
	Enalapril			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ferric Hydroxide Polymaltose Complex	S	Unknown	Not Reported
Ferrous Fumarate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Insulin	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Leflunomide	S		Not Reported
Metformin	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S		Not Reported
Methotrexate	S		Not Reported
Prednisone	S	Unknown	Not Reported
Protopin	S	Intramuscular	Not Reported
Ranitidine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S		Not Reported
Remicade	S		Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Testosterone	S	Unknown	Not Reported
Acetazolamide	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829521	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2607349		21 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatitis; Hypocoagulable State; Pancreatitis Acute	Tocilizumab			S	Intravenous (not otherwise specified)	Desconocida		Not Reported	
	Tocilizumab			S				Not Reported	
	Ambisome			S	Intravenous (not otherwise specified)			Not Reported	
	Hidroxicloroquina Sulfato			S	Oral	400mg/24h		Not Reported	
	Hidroxicloroquina Sulfato			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Linezolid

S

Intravenous (not
otherwise specified)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829594	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1051133		31 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic; Off Label Use	Lopinavir/Ritonavir Mylan			S	Oral	4 Dosage Form		Mylan
	Plaquenil /00072603/			S	Oral	100 Milligram, Qd		Mylan
	Calcidose /07357001/			C		Unk		Mylan
	Piperacilline/Tazobactam			C		Unk		Mylan
	Doliprane			C		Unk		Mylan
	Rocephine			C		Unk		Mylan
	Sodium Bicarbonate			C		Unk		Mylan
	Furosemide			C		Unk		Mylan
	Amlodipine			C		Unk		Mylan
	Diffu K			C		Unk		Mylan
	Renvela			C		Unk		Mylan
	Calciparine			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829602	EXPEDITED (15-DAY)		CA, OT	FR-MYLANLABS-2020M1051130			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Achromotrichia Congenital; Foetal Exposure During Pregnancy	Parlodel			S	Transplacental	20 Milligram, Qd		Mylan
	Hydrocortisone Roussel			S	Transplacental	100 Milligram, Qd		Mylan
	/00028601/ Zithromax			S	Transplacental	250 Milligram, Qd		Mylan
	Plaquenil /00072603/			S	Transplacental	600 Milligram, Qd		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829606	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1051120		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Qd (500 Mg Dia)		Not Reported	
	Enoxaparin			S	Subcutaneous	80 Milligram, Bid (80 Mg Cada 12h)		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Milligram, Qd (600 Mg)		Mylan	
	Hidroxicloroquina /00072601/			S	Oral	400 Milligram, Qd (400 Mg Dia)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829680	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204768		60 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Reuquinol			S	Oral	400 Mg, Daily ((Given In 2 Divided Doses Every 12 Hours)		Not Reported	
	Reuquinol			S		400 Mg, Daily (Given In 2 Divided Doses Every 12 Hours)		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 2x/Day		Not Reported	
	Oseltamivir			C	Oral	75 Mg, 2x/Day		Not Reported	
	Tazocin			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day (Every 8 Hours)		Not Reported	
	Tazocin			C	Intravenous (not	4.5 G, 4x/Day (Every		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vancomycin Hydrochloride	C	otherwise specified)	6hours)	Not Reported
Vancomycin Hydrochloride	C	Intravenous (not otherwise specified)	1 G, 2x/Day (Every 12hours)	Not Reported
Dobutamine	C		Unk	Not Reported
Sodium Bicarbonate	C		Unk	Not Reported
Cis [Cisatracurium Besilate]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Sodium Chloride	C		Unk	Not Reported
Dopacris	C	Intravenous (not otherwise specified)	250 Mg, As Needed	Not Reported
Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Nexium Mups [Esomeprazole Magnesium]	C		20 Mg, 1x/Day	Not Reported
Lipless	C		Unk	Not Reported
Hydrochlorothiazide	C		Unk	Not Reported
Trezor [Rosuvastatin Calcium]	C		Unk	Not Reported
Metformin	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Tamiram	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829730	EXPEDITED (15-DAY)		HO, LT	CA-ROCHE-2606587		12 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Arthritis; Arthropathy;	Actemra			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased;	Actemra	S	otherwise specified)	Not Reported
Condition Aggravated; Diarrhoea; Dizziness;	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Drug Ineffective; Drug Intolerance; Drug Specific Antibody Present;	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Gastroenteritis Viral; Human Anti-Human Antibody Test; Human Antichimeric Antibody Positive; Hypocalcaemia;	Naproxen	S	Intravenous (not otherwise specified)	Not Reported
Hypokalaemia;	Anakinra	S	Unknown	Not Reported
Hypotension;	Anakinra	S	Subcutaneous	Not Reported
Immunodeficiency;	Anakinra	S	Subcutaneous	Not Reported
Impaired Quality Of Life; Joint Destruction; Joint Injury; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea;	Anakinra	S	Unknown	Not Reported
Obesity; Off Label Use; Pleural Effusion;	Enbrel	S	Subcutaneous	Not Reported
Polyarthritis; Prescribed Underdose; Pyrexia; Red Blood Cell Sedimentation Rate Increased;	Enbrel	S	Subcutaneous	Not Reported
Rheumatoid Arthritis; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Oral	Not Reported
	Immune Globulin (Immunoglobulins Nos)	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infliximab	S	otherwise specified)	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Triamcinolone	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Intramuscular	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Triamcinolone Hexacetonide	S	Other	Not Reported
Triamcinolone Hexacetonide	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829735	DIRECT	Y	OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Heart Rate Increased; Hypertension; Nervousness; Panic Attack	Hydroxychloroquine			S				Dr Reddys	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829746	DIRECT		DS, OT			61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease; Gingival Erosion; Tooth Disorder; Tooth Fracture	Orencia 125 Mgs	Y		S	Subcutaneous	Quantity:1 Injection(S);Other Frequency:Once A Week;		Unknown	
	Hydroxychloroquine	Y		S	Oral	Quantity:1 Capsule(S);		Prasco	
	Morphine 30mg			C				Not Reported	
	Oxycodone			C				Not Reported	
	Iron Tablets Tablet			C				Not Reported	
	Spiriva Respimat 2.5mg			C				Not Reported	
	Cetirizine 10mg			C				Not Reported	
	Topiramate 100mg			C				Not Reported	
	Aspirin 81mg			C				Not Reported	
	Lisinopril 5mg			C				Not Reported	
	Folic Acid 1mg			C				Not Reported	
	Prednisone 4mgs			C				Not Reported	
	Calcium 600mgs			C				Not Reported	
	Vitamin A			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Vitamin B 12			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829863	EXPEDITED (15-DAY)		HO	ES-CADILA HEALTHCARE			Unknown	ESP

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

LIMITED-ES-ZYDUS-051271

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hyponatraemia	Azithromycin			S	Oral	500 Mg Dia		ZyduS Pharm
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr		Not Reported
	Symbicort			S	Respiratory (inhalation)	2-2-2		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg Dia		Not Reported
	Salbutamol			S	Respiratory (inhalation)	2-2-2 Inh		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829864	EXPEDITED (15-DAY)		OT	ES-CADILA HEALTHCARE LIMITED-ES-ZYDUS-051272			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azithromycin			S	Oral	500 Mg Dia		ZyduS Pharm
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Hidroxicloroquina [Hydroxychloroquine]			S	Oral	400 Mg Dia		Not Reported
	Dexametasona [Dexamethasone]			S	Intravenous (not otherwise specified)	20 Mg		Not Reported
	Ceftriaxona [Ceftriaxone]			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported
	Enoxaparina			S	Subcutaneous	80 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829970	EXPEDITED (15-DAY)		OT	JP-ADVANS PHARMA-GSH201805-001826			Unknown	JPN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Tacrolimus Monohydrate			S	Oral	4 Mg, Qd		Not Reported
	Prednisolone			C		Unk		Not Reported
	Onealfa			C		Unk		Not Reported
	Onealfa			C				Not Reported
	Aspartate Comps			C		Unk		Not Reported
	Aspartate Comps			C				Not Reported
	Takepron			C		Unk		Not Reported
	Bayaspirin			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Avapro			C		Unk		Not Reported
	Metgluco			C		Unk		Not Reported
	Myslee			C		Unk		Not Reported
	Hyalein Eye Drops			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830009	EXPEDITED (15-DAY)		HO, OT	FR-ASTRAZENECA-2020SE66003		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised Oedema; Pneumonia;	Inexium			S	Intravenous (not otherwise specified)	40 Mg, Qd		Astrazeneca
	Tazocilline			S	Unknown	Unk		Not Reported
	Perfalgan			S	Unknown	1 G, Qid If Temperature Is Greater To 38.24.0g Unknown		Not Reported
	Lovenox			S	Subcutaneous	Unk Unk, Bid (8000 Ui)		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Rocephine			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pseudomonas Infection; Quarantine; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Mucomyst	S	Unknown	1 Df, Qid (Sachet Sng)4.0df Unknown	Not Reported
	Dextro [Dextromethorphan Hydrobromide]	S	Unknown	Unk	Not Reported
	Catapressan	S	Unknown	Unk	Not Reported
	Claventin [Clavulanic Acid/Ticarcillin]	S	Unknown	Unk	Not Reported
	Lederfoline	S	Unknown	Unk	Not Reported
	Tavanic	S	Unknown	500 Mg, Bid	Not Reported
	Eupressyl	S	Unknown	Unk	Not Reported
	Fortum	S	Unknown	2 G, Tid	Not Reported
	Zithromax	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Tranxene	S	Unknown	2.5 Mg Pre Hour	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830033	EXPEDITED (15-DAY)		OT	US-ADVANTZ PHARMA- 202005005516			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Lupus Nephritis; Off Label Use; Proteinuria; Treatment Noncompliance	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Lovenox			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830092	EXPEDITED (15-DAY)		DS	CA-ROCHE-2599257		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort;	Actemra	S	Subcutaneous	Not Reported
Alopecia; Anti-Cyclic	Simponi	S	Subcutaneous	Not Reported
Citrullinated Peptide	Arava	S	Oral	Not Reported
Antibody Positive;	Cetirizine Hydrochloride	S	Unknown	Not Reported
Arthropathy;	Cimzia	S	Subcutaneous	Not Reported
Contraindicated Product	Cortisone Acetate	S	Topical	Not Reported
Administered; Discomfort;	Desoximetasone	S	Oral	Not Reported
Drug Ineffective; Drug	Diclofenac	S	Unknown	Not Reported
Intolerance; Duodenal	Enbrel	S	Subcutaneous	Not Reported
Ulcer Perforation; Fatigue;	Folic Acid	S	Unknown	Not Reported
Glossodynia; Hand	Folic Acid	S	Unknown	Not Reported
Deformity; Helicobacter	Humira	S	Subcutaneous	Not Reported
Infection; Hepatic Enzyme	Hydroxychloroquine	S	Oral	Not Reported
Increased;	Hydroxychloroquine	S	Unknown	Not Reported
Hypersensitivity; Infusion	Methotrexate	S	Oral	Not Reported
Related Reaction; Pain;	Methotrexate	S	Oral	Not Reported
Pemphigus; Pericarditis;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Pregnancy; Rash;	Phthalylsulfathiazole	S	Unknown	Not Reported
Rheumatoid Arthritis;	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Swelling; Synovitis;	Prednisone	S	Oral	Not Reported
Systemic Lupus	Prednisone	S	Oral	Not Reported
Erythematous; Wound	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported
	Sulfathalidine	S	Oral	Not Reported

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Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Topical [Desoximetasone]	S	Cutaneous	Not Reported
Alendronate Sodium	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830175	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1052059		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine			S	Oral	Approximately 10-11 Gram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830229	EXPEDITED (15-DAY)		OT	NVSC2020CA143801			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angiopathy; Drug Ineffective; Panniculitis	Colchicine			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Novartis	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Gen-Hydroxychloroquine			S	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830313	EXPEDITED (15-DAY)		OT	FR-009507513-2005FRA006026		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Celestene Chronodose			S	Intravenous (not	1 Dosage Form, Qd (5,70		Merck	

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		otherwise specified)	Mg/ML, Suspension Injectab)	
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 Gram, Qd	Not Reported
Zithromax	S	Oral	250 Milligram, Qd	Not Reported
Plaquenil	S	Oral	600 Milligram, Qd	Not Reported
Lovenox	C		Unk, Mammal/Pork/Intestinal Mucosa	Not Reported
Potassium Acetate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830468	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA- 2020VAL000434			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Demerol			S	Unknown	Unk		Validus
	Pethidine Hydrochloride			S	Unknown	Unk		Validus
	Prednisone			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Bisoprolol			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Norfloxacin			S	Unknown	Unk		Not Reported
	Plaquenil /00072603/			S	Oral	400 Mg, Unk		Not Reported

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Levofloxacin	S	Unknown	Unk	Not Reported
Arthrotec	S	Unknown	Unk	Not Reported
Arthrotec	S	Intracardiac	Unk	Not Reported
Ceclor	S	Unknown	Unk	Not Reported
Celebrex	S	Oral	200 Mg, Qd	Not Reported
Humira	S	Subcutaneous	400 Mg, Unk	Not Reported
Lyrica	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830774	EXPEDITED (15-DAY)	HO		CA-JNJFOC-20200525219		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate	Remicade			S	Intravenous (not otherwise specified)			Janssen	
Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Alendronate			S	Oral			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	

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Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830784	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526261		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Codeine			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported

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Sulfasalazine			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17830922	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1051633		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		500 Milligram, Qd		Not Reported	
	Kaletra			S		1 Dosage Form, Bid		Mylan	
	Interferon Beta			S		250 Milligram, Q2d		Mylan	
	Hidroxycloquina /00072601/			S		200 Milligram, Bid		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17832245	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605648		45 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Off Label Use; Pain; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Mycophenolate Mofetil	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	10657398	EXPEDITED (15-DAY)		DS	FR-ASTRAZENECA-2014SE95951		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gait Disturbance; Peripheral Sensorimotor Neuropathy	Inexium			S	Oral			Astrazeneca
	Fosamax			S	Oral			Not Reported
	Tahor			S	Oral			Not Reported
	Lexomil Roche			S	Oral			Not Reported
	Cacit Vitamine D3			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Cymbalta			S	Oral			Not Reported
	Avodart			S	Oral			Not Reported
	Lasilix			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Forlax			S	Oral			Not Reported
	Metoject			S	Subcutaneous			Not Reported
	Skenan			S	Oral			Not Reported

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Cortancyl	S	Oral	Not Reported
Salazopyrine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	12676043	EXPEDITED (15-DAY)		DS, OT	CA-SA-2015SA146389		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Arava			S	Oral	20 Mg, Unk		Sanofi
Adverse Event; Alopecia;	Leflunomide			S	Oral	Unk		Sanofi
Anti-Cyclic Citrullinated	Leflunomide			S	Unknown	Unk		Sanofi
Peptide Antibody Positive;	Plaquenil			S	Oral	400 Mg,Qd		Sanofi
Arthropathy; Condition	Plaquenil			S	Oral	1 Df, Qd		Sanofi
Aggravated;	Methotrexate			S	Oral	25 Mg,Unk		Not Reported
Contraindicated Product	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
Administered; Discomfort;	Methotrexate			S	Unknown	Unk		Not Reported
Drug Ineffective; Drug	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
Intolerance; Duodenal	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
Ulcer Perforation; Fatigue;	Methotrexate			S	Unknown	Unk		Not Reported
Glossodynia; Hand	Methotrexate			S	Oral	25 Mg, Unk		Not Reported
Deformity; Helicobacter	Methotrexate			S	Oral	20 Mg, Qd		Not Reported
Infection; Hepatic Enzyme	Methotrexate			S	Oral	1 Df, Qd		Not Reported
Increased; Hip	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Arthroplasty;	Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
Hypersensitivity; Infusion	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Related Reaction; Joint	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Swelling; Knee	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
Arthroplasty; Live Birth;	Hydroxychloroquine Sulfate			S	Subcutaneous	4000 Mg, Qd		Sanofi
Maternal Exposure During	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
Pregnancy; Pain;	Hydroxychloroquine Sulfate			S	Oral	Unk		Sanofi
Pemphigus; Pericarditis;	Pseudoephedrine Hydrochloride			S	Unknown	25 Mg, Unk		Sanofi
Product Use Issue; Rash;	Desoximetasone			S	Oral	Unk		Sanofi
Rheumatoid Arthritis;	Desoximetasone			S	Oral	Unk		Sanofi
Rheumatoid Factor	Desoximetasone			S	Cutaneous	Unk		Sanofi
Positive; Swelling;								
Synovitis; Systemic Lupus								
Erythematousus; Treatment								
Failure; Wound								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alendronate Sodium	S	Oral	Unk	Not Reported
Alendronate Sodium	S		Unk	Not Reported
Alendronate Sodium	S	Oral	Unk	Not Reported
Diclofenac Sodium	S	Unknown	Unk	Not Reported
Sarilumab	S	Unknown	Unk	Sanofi
Hydrocortisone Acetate	S	Subcutaneous	Unk	Sanofi
Hydrocortisone Acetate	S	Unknown	Unk	Sanofi
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	1 G,Bid	Not Reported
Sulfasalazine	S	Unknown	500 Mg	Not Reported
Sulfasalazine	S		1 G, 1 In 12 Hours	Not Reported
Sulfasalazine	S	Oral	2 Df, Qd	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported
Cortisone Acetate	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	25 Mg, Unk	Not Reported
Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown	10 Mg, Unk	Not Reported
Hydroxychloroquine	S	Oral	Unk	Sanofi
Hydroxychloroquine	S	Oral	Unk	Sanofi
Folic Acid	S	Unknown	5 Mg, Unk	Not Reported
Folic Acid	S	Unknown	1 Mg, Unk	Not Reported
Folic Acid	S	Unknown	5 Mg	Not Reported
Folic Acid	S	Unknown	25 Mg, Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Unknown	Unk	Not Reported
Actemra	S	Subcutaneous	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S	Unknown	Unk	Not Reported
Cimzia	S	Subcutaneous	Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Cortisone	S	Oral	Unk Unk, Prn	Not Reported
Cortisone	S	Oral	Unk	Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Enbrel	S	Subcutaneous	Unk, Prn	Not Reported
Enbrel	S	Unknown	Unk	Not Reported
Stelara	S	Unknown	Unk	Not Reported
Sulfathalidine	S	Unknown	Unk	Not Reported
Golimumab	S	Subcutaneous	Unk	Not Reported
Golimumab	S	Unknown	Unk	Not Reported
Xeljanz	S		Unk	Not Reported
Xeljanz	C	Unknown	5 Mg, Bid	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Leflunomide	C	Unknown	Unk	Not Reported
Atasol [Paracetamol]	C	Unknown	Unk	Not Reported
Salazopyrin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	12864344	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717965			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthralgia; Arthropathy;	Rituxan			S	Intravenous (not			Not Reported
Blood Glucose Increased;					otherwise specified)			
Blood Pressure Increased;	Actemra			S	Unknown			Not Reported
C-Reactive Protein	Arava			S	Unknown	Therapy Duration: 4		Not Reported
Abnormal; Condition						Months		
Aggravated;	Arava			S	Oral			Not Reported
Contraindicated Product	Arava			S	Unknown			Not Reported
Administered; Drug	Arava			S	Unknown			Not Reported
Hypersensitivity; Drug	Cimzia			S	Subcutaneous			Not Reported
Ineffective; Drug	Cimzia			S	Subcutaneous			Not Reported
Intolerance; Fatigue;	Enbrel			S	Unknown	On 10/Feb/2016, She		Not Reported
Femur Fracture; Gait						Received Last Dose Of		
Disturbance; Gastric						Etanercept (Enbrel)		
Disorder; Glycosylated	Enbrel			S	Subcutaneous			Not Reported
Haemoglobin Increased;	Enbrel			S	Unknown			Not Reported
Heart Rate Increased;	Enbrel			S	Unknown			Not Reported
Hepatic Enzyme	Enbrel			S	Unknown			Not Reported
Increased; Infection;	Enbrel			S	Unknown			Not Reported
Intentional Product	Humira			S	Subcutaneous			Not Reported
Misuse; Joint Swelling;	Orencia			S	Unknown			Not Reported
Loss Of Personal	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Independence In Daily	Sulfate]							
Activities; Lymphocyte	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported
Count Increased; Malaise;	Sulfate]							
Musculoskeletal Stiffness;	Remicade			S	Intravenous (not			Not Reported
Nasal Congestion;					otherwise specified)			
Nasopharyngitis; Nausea;	Simponi			S	Subcutaneous			Not Reported
Nephrolithiasis; Neutrophil	Simponi			S	Subcutaneous			Not Reported
Count Increased; Off	Sulfasalazine			S	Unknown			Not Reported
Label Use; Osteopenia;	Sulfasalazine			S	Oral			Not Reported
Pain; Pain In Extremity;	Sulfasalazine			S	Oral			Not Reported
Pain; Pain In Extremity;	Tylenol			S	Unknown			Not Reported
Peripheral Swelling;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Pneumonia; Pyrexia;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Rash; Red Blood Cell								
Sedimentation Rate								
Increased; Red Cell								
Distribution Width								
Increased; Rheumatoid								
Arthritis; Somnolence;								
Somnolence; Synovitis;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tooth Abscess; Treatment Failure; Visual Impairment; Weight Decreased; White Blood Cell Count Increased	Hydroxychloroquine Sulfate	S	Subcutaneous		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	S			Not Reported
	Apo-Acetaminophen	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Doxycycline Hyclate	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Apo-Hydro	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Methotrexate	C	Unknown	25 Mg/MI	Not Reported
	Meloxicam	C			Not Reported
	Synthroid	C			Not Reported
	Tylenol	C			Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	As Required	Not Reported
	Celebrex	C	Oral		Not Reported
	Hydromorphone Hydrochloride	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	13058844	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015725		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; Fracture; General Physical Health Deterioration; Hepatitis; Immobile; Loss Of Personal Independence In Daily Activities; Lower	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Prednisone			S	Unknown	Unk		Apotex
	Apo-Prednisone			S	Oral	20 Mg, Qd		Apotex
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Celecoxib			S	Unknown	Unk		Apotex
	Risedronate			S	Unknown	Unk		Apotex
	Risedronate			S	Oral	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Sulfasalazine	S	Oral	500 Mg, Unk	Not Reported
	Sulfasalazine	S	Oral	50 Mg, Unk	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Actonel	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Methotrexate Sodium	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Methotrexate Sodium	S	Unknown	Unk, Q.Wk.	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prolia	S	Subcutaneous	Unk	Not Reported
	Prolia	S			Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk, Q.Wk.	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg, Q.Wk.	Not Reported
	Prednisolone Sodium Phosphate	S	Unknown	Unk	Not Reported
	Prednisolone Sodium Phosphate	S	Ophthalmic	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, Bid	Not Reported
	Cyclobenzaprine	C	Unknown	10 Mg, Unk	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Qd	Not Reported
	Desoximetasone	C	Unknown	5 Mg, Unk	Not Reported
	Leflunomide	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone Acetate	C	Unknown	5 Mg, Qd	Not Reported
Tylenol /00020001/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	13111870	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1717236			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Abnormal; Condition Aggravated;	Enbrel			S	Subcutaneous	Every Week		Not Reported
Contraindicated Product	Hydroxychloroquine			S	Unknown			Not Reported
Administered; Drug	Sulfasalazine			S	Oral			Not Reported
Hypersensitivity; Drug Ineffective; Drug	Rho(D) Immune Globulin			S	Unknown			Not Reported
Intolerance;	Humira			S	Subcutaneous	4 Years		Not Reported
Gastrointestinal Toxicity;	Arava			S	Unknown			Not Reported
Hepatotoxicity; Infection;	Benzalkonium Chloride			S	Unknown			Not Reported
Joint Injury; Joint Stiffness;	Boric Acid			S	Unknown			Not Reported
Joint Swelling;	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
Musculoskeletal Pain;	Cimzia			S	Unknown			Not Reported
Musculoskeletal Stiffness;	Disodium Edetate			S	Unknown			Not Reported
Neoplasm Malignant; Pain	Gold			S	Unknown			Not Reported
In Extremity; Pulmonary	Tofacitinib Citrate			S	Subcutaneous			Not Reported
Toxicity; Rheumatoid	Sodium Borate			S	Unknown			Not Reported
Arthritis; Therapeutic	Simponi			S	Unknown			Not Reported
Product Effect Incomplete;	Rituximab			S	Unknown			Not Reported
Therapy Non-Responder;	Phenylephrine Hcl			S	Unknown			Not Reported
Treatment Failure	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Subcutaneous		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Methotrexate Sodium	S	Oral	Qwk	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral		Not Reported
	Ibuprofen	C	Oral		Not Reported
	Celebrex	C	Oral		Not Reported
	Lipitor [Atorvastatin Calcium]	C	Oral		Not Reported
	Prednisone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	13212360	EXPEDITED (15-DAY)		OT	CA-SA-2015SA111836		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Plaquenil			S	Unknown	Unk Unk,Unk		Sanofi
Breast Cancer; Breast	Arava			S	Unknown	Unk Unk,Unk		Sanofi
Cancer Stage Iii; Condition	Sodium Aurothiomalate			S	Intramuscular	Unk Unk,Unk		Not Reported
Aggravated;	Methotrexate Bellon			S	Subcutaneous	Unk Unk,Unk		Not Reported
Contraindicated Product	Sulfasalazine			S	Unknown	Unk Unk,Unk		Not Reported
Administered; Depression;	Hydroxychloroquine			S				Sanofi
Diarrhoea; Drug	Hydroxychloroquine Sulfate			S				Sanofi
Ineffective; Drug	Methotrexate			S	Subcutaneous			Not Reported
Ineffective; Drug	Methotrexate			S	Subcutaneous	Unk		Not Reported
Intolerance; Gait	Enbrel			S	Subcutaneous	Unk Unk,Unk		Not Reported
Disturbance; Gait Inability;	Orencia			S	Intravenous (not	Unk Unk,Unk		Not Reported
Joint Range Of Motion					otherwise specified)			
Decreased; Memory	Rituxan			S	Intravenous (not	Unk Unk,Unk		Not Reported
Impairment;								
Musculoskeletal Disorder;								
Nausea; Ovarian Cancer;								
Rheumatoid Arthritis;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Nodule; Sleep Disorder; Therapeutic Product Effect Incomplete; Treatment Noncompliance	Simponi Gold Humira Rituximab	S S S S	otherwise specified) Subcutaneous Subcutaneous	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	13657154	EXPEDITED (15-DAY)		DS, HO, OT	CA-SA-2017SA105779		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Arthralgia; Aspartate	Hydroxychloroquine Leflunomide Leflunomide			S S S	Oral Oral Oral	200 Mg, Qd 20 Mg 20 Mg		Sanofi Sanofi Sanofi
Aminotransferase Increased; Basal Cell Carcinoma; Blood	Sulfasalazine Sulfasalazine			S S	Unknown	Unk Unk,Unk 500 Mg		Not Reported Not Reported
Parathyroid Hormone Decreased; C-Reactive Protein Increased;	Alendronate Sodium Alendronate Sodium			S S	Unknown Unknown	70 Mg,Qw Unk Unk,Unk		Not Reported Not Reported
Contraindicated Product Administered; Drug Eruption; Drug	Codeine Methotrexate			S S	Unknown Subcutaneous	Unk Unk,Unk 10 Mg, Qw		Not Reported Not Reported
Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug	Methotrexate Methotrexate Methotrexate			S S S	Subcutaneous Subcutaneous Oral	15 Mg 10 Mg,Qw		Not Reported Not Reported Not Reported
Intolerance; Drug Tolerance Decreased; Erythema; Erythema; Granuloma Skin;	Methotrexate Methotrexate Methotrexate			S S S	Subcutaneous Subcutaneous	17.5 Mg 12.5 Mg, Qw 12 Mg, Qw		Not Reported Not Reported Not Reported
Hypercalcaemia; Hypersensitivity; Inflammation; Infusion	Methotrexate Methotrexate Methotrexate			S S S	Subcutaneous	10 Mg, Qw 15 Mg		Not Reported Not Reported Not Reported
Related Reaction; Loss Of Personal Independence In Daily Activities;	Methotrexate Methotrexate			S S	Subcutaneous Subcutaneous	17.5 Mg, Qw 10 Mg, Q4w		Not Reported Not Reported
Musculoskeletal Stiffness; Pain; Panniculitis; Peripheral Swelling;	Methotrexate Methotrexate			S S		12.5 Mg, Q4w 12 Mg		Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use Issue;	Methotrexate	S	Subcutaneous	15 Mg, Qw	Not Reported
Pruritus; Rash; Rash;	Methotrexate	S	Oral	10 Mg, Q4w	Not Reported
Rash Pruritic; Red Blood	Methotrexate	S		10 Mg, Qw	Not Reported
Cell Sedimentation Rate	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
Increased; Rheumatoid	Methotrexate	S	Subcutaneous	17.5 Mg, Qw	Not Reported
Arthritis; Rheumatoid	Methotrexate	S		12.5 Mg, Qw	Not Reported
Arthritis; Rheumatoid	Methotrexate	S		10 Mg, Qw	Not Reported
Nodule; Skin Necrosis;	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
Skin Ulcer; Therapeutic	Methotrexate	S		12.5 Mg, Qw	Not Reported
Product Effect Decreased;	Methotrexate	S		10 Mg, Qw	Not Reported
Therapeutic Response	Methotrexate	S		12.5 Mg, Qw	Not Reported
Decreased; Ulcer	Methotrexate	S		10 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Qw	Not Reported
	Methotrexate	S		12.5 Mg, Qw	Not Reported
	Methotrexate	S		10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	15.5 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	70 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	10 Mg, Qw	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Mg, Qw	Not Reported
	Methotrexate	S		17.5 Mg, Qw	Not Reported
	Methotrexate	S		15 Mg, Q4w	Not Reported
	Methotrexate	S		12 Mg, Q4w	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Mg, Q4w	Not Reported
	Methotrexate	S	Oral	25 Mg, Qw	Not Reported
	Alendronic Acid	S		70 Mg, Qw	Not Reported
	Myochrysine	S	Intramuscular	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qm	Not Reported
	Myochrysine	S	Parenteral	50 Mg, Qm	Not Reported
	Myochrysine	S	Intramuscular	25 Mg, Qw	Not Reported
	Methotrexate Sodium	S	Oral	10 Mg, Qow	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	S	Unknown	680 Mg,Qm	Not Reported
Actemra	S	Unknown	360 Mg,Qm	Not Reported
Actemra	S		380 Mg	Not Reported
Actemra	S		360 Mg, Qm	Not Reported
Enbrel	S	Unknown	50 Mg,Biw	Not Reported
Enbrel	S	Unknown	25 Mg,Biw	Not Reported
Enbrel	S		Unk	Not Reported
Enbrel	S		50 Mg, Qw	Not Reported
Humira	S	Subcutaneous	40 Mg,Qow	Not Reported
Humira	S		40 Unk	Not Reported
Humira	S	Subcutaneous	40 Mg, Qow	Not Reported
Orencia	S	Unknown	780 Mg,Qw	Not Reported
Orencia	S		780 Mg	Not Reported
Orencia	S		780 Mg, Qw	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk Unk,Unk	Not Reported
Remicade	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S		Unk	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg,Bid	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	1000 Mg	Not Reported
Rituximab	S		1000 Mg, Bid	Not Reported
Tocilizumab	S		680 Mg, Q4w	Not Reported
Ciclosporin	C	Unknown	150 Mg,Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Prednisolone	C	Unknown	10 Mg,Unk	Not Reported
	Prednisone	C	Unknown	10 Mg,Qd	Not Reported
	Prednisone	C		10 Mg, Qd	Not Reported
	Xeljanz	C			Not Reported
	Alendronate Sodium	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	16695071	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-079550			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Apixaban			S	Unknown	2.5 Milligram, Bid		Bristol Myers Squibb
	Apixaban			S	Unknown	2 Dosage Form, Qd		Bristol Myers Squibb
	Volibris			S	Oral	30 Milligram, Qd		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Lyrica			S	Unknown	100 Milligram, Tid		Not Reported
	Quensyl			S	Unknown	40 Mg, Bid (80mg/Day)		Not Reported
	Quensyl			S	Unknown	20 Milligram, Bid		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Roactemra			S	Subcutaneous	162 Milligram, Qwk		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Milligram, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid		Not Reported
	Omeprazole			S	Oral	20 Milligram		Not Reported
	Ramipril			S	Oral	1 Dosage Form, Bid		Not Reported
	Ramipril			S	Unknown	5 Milligram, Qd		Not Reported
	Sildenafil Citrate			S	Unknown	60 Milligram, Daily Dose		Not Reported
	Pregabalin			S	Unknown	100 Milligram, Tid		Not Reported
	Pregabalin			S	Unknown	1 Dosage Form		Not Reported

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Ambrisentan	S	Unknown	30 Milligram, Qd	Not Reported
Ambrisentan	S	Oral	1 Dosage Form, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17024269	EXPEDITED (15-DAY)		OT	DE-ADVANSZ PHARMA-GSH201908-001839			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Hydroxychloroquine			S	Unknown	20 Mg, Bid (40 Mg/Day)		Concordia
	Hydroxychloroquine			S	Unknown	40 Mg, Bid (80mg/Day)		Concordia
	Ramipril			S	Oral	1 Dosage Form, Bid, (1 - 0 - 1)		Not Reported
	Ramipril			S	Unknown	5 Mg, Qd		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Lyrica			S	Unknown	1 Dosage Form, Tid		Not Reported
	Lyrica			S	Unknown	100 Mg, Tid		Not Reported
	Omeprazole			S	Oral	1 Dosage Form, Bid (1-0-1)		Not Reported
	Omeprazole			S	Oral	20 Mg, Bid		Not Reported
	Volibris			S	Oral	1 Dosage Form, Qd		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Volibris			S	Unknown	Unk		Not Reported
	Volibris			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	1 Dosage Form, Qd		Not Reported
	Spasmolyt			S	Unknown	15 Mg, Qd		Not Reported
	Spasmolyt			S	Unknown	30 Mg, Qd		Not Reported
	Apixaban			S	Unknown	2.5 Mg, Bid		Not Reported
	Apixaban			S	Unknown	2 Dosage Form, Qd		Not Reported
	Roactemra			S	Subcutaneous	162 Mg, Qw, Solution For Injection In Pre-Filled Syringe		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
	Sildenafil Citrate	S	Unknown	60 Mg, Qd	Not Reported
	Ambrisentan	S	Oral	30 Mg, Qd	Not Reported
	Ambrisentan	S	Oral	1 Dosage Form, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17088021	NON-EXPEDITED			US-UCBSA-2018027063			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Cimzia			S				Not Reported
	Methotrexate			S				Not Reported
	Plaquenil			S				Not Reported
	Prednisone			S				Not Reported
	Remicade			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17090199	NON-EXPEDITED			US-UCBSA-2018021530			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Cimzia			S		Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Dose		Not Reported
	Methotrexate			S		Unknown		Not Reported
	Hydroxychloroquine			S		Unknown		Not Reported
	Leflunomide			S		Unknown Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17104636	NON-EXPEDITED			US-UCBSA-2017051005			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Adverse Drug Reaction; Drug Intolerance	Cimzia	S		Unk	Not Reported
	Methotrexate	S		Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S		Unk	Not Reported
	Hydroxychloroquine	S		Unk	Not Reported
	Tofacitinib	C	Oral	1 Mg, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17104656	NON-EXPEDITED			US-UCBSA-2018003810		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Butterfly Rash; Drug Ineffective; Gastrointestinal Disorder; Mental Status Changes; Pruritus	Cimzia			S		Unk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S		Unk		Not Reported
	Plaquenil			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17208175	NON-EXPEDITED			US-UCBSA-2017031305			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia Of Chronic Disease; Blood Prolactin Decreased; Blood Thyroid Stimulating Hormone Decreased; Essential Hypertension; Fall; Fibromyalgia; Gait Disturbance; Immunoglobulins Decreased; Insomnia; Osteoarthritis; Osteopenia; Pain; Rheumatoid Arthritis; Spondyloarthropathy;	Cimzia			S		Unk		Not Reported
	Cetirizine Hydrochloride			S		Unk		Not Reported
	Enbrel			S		Unk		Not Reported
	Enbrel			S				Not Reported
	Prolia			S		Unk		Not Reported
	Methotrexate Sodium			S		Unk		Not Reported
	Tofacitinib Citrate			S		Unk		Not Reported
	Actemra			S		Unk		Not Reported
	Remicade			S		Unk		Not Reported

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Synovitis; Type V Hyperlipidaemia	Humira	S		40 Mg, Weekly (Qw)	Not Reported
	Humira	S			Not Reported
	Orencia	S		Unk	Not Reported
	Plaquenil	S		Unk	Not Reported
	Arava	S	Oral	20 Mg Daily	Not Reported
	Aranesp	C			Not Reported
	Oxycodone	C			Not Reported
	Abilify	C		Unk	Not Reported
	Advair	C			Not Reported
	Atenolol	C			Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Crestor	C			Not Reported
	Cytomel	C			Not Reported
	Dorzolamide Hcl	C		Unk	Not Reported
	Duloxetine Hydrochloride	C		Unk	Not Reported
	Duoneb	C			Not Reported
	Famotidine	C			Not Reported
	Finasteride	C			Not Reported
	Furosemide	C			Not Reported
	Gabapentin	C			Not Reported
	Leflunomide	C			Not Reported
	Lovaza	C			Not Reported
	Medrol	C			Not Reported
	Myrbetriq	C		Unk	Not Reported
	Nexium	C			Not Reported
	Fish Oil W/Tocopherol	C			Not Reported
	Oxycodone Hcl	C			Not Reported
	Prochlorperazine Maleate	C			Not Reported
	Relpax	C			Not Reported
	Singulair	C			Not Reported
	Soma	C			Not Reported
	Sulfazine Ec	C			Not Reported
	Synthroid	C			Not Reported
	Tamsulosin Hcl	C			Not Reported
	Topamax	C			Not Reported
	Topiramate	C			Not Reported
	Triamterene/Hctz	C			Not Reported
	Voltaren	C			Not Reported
	Xalatan	C			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Cymbalta	C	Not Reported
	Vicodin	C	Not Reported
	Vicodin	C	Not Reported
	Klonopin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17235412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508236			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Drug Ineffective; Hepatitis; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S				Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17259883	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518735			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Joint Swelling; Pain; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17285802	EXPEDITED (15-DAY)		OT	CA-ROCHE-2523752		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown	Solution		Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Desoximetasone			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17288398	EXPEDITED (15-DAY)		HO, LT, OT	CA-SA-2020SA013858		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Ill-Defined Disorder; Infection; Kidney Infection; Musculoskeletal Disorder; Off Label Use; Rheumatoid Arthritis; Sepsis; Therapeutic Response Decreased	Arava			S	Unknown	Unk		Sanofi	
	Methotrexate			S	Oral	4 Df, Qw		Not Reported	
	Methotrexate			S	Oral	Qw (1 Every 1 Weeks)		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Sanofi	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Orencia			S	Unknown	Unk		Not Reported	
	Remicade			S	Unknown	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17290629	EXPEDITED (15-DAY)		DE	CA-ROCHE-2528043		41 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diffuse Large B-Cell Lymphoma	Rituximab			S	Unknown			Not Reported	
	Rituximab			S				Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S				Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Cyclophosphamide			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Unknown			Not Reported	
	Prednisone Acetate			S	Unknown			Not Reported	
	Prednisone Acetate			S				Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S				Not Reported	

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Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S		Not Reported
Prednisone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17305038	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013783			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Deformity; Finger Deformity; Foot Deformity; Hand Deformity; Hepatic Failure; Hypersensitivity; Infection; Knee Arthroplasty; Ocular Icterus; Osteoarthritis; Pain; Pancreatitis; Upper Limb Fracture; Wrist Deformity	Arava			S		Unk		Sanofi
	Celecoxib			S		Unk		Not Reported
	Diclofenac Sodium			S		Unk		Not Reported
	Plaquenil			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Methotrexate			C	Subcutaneous	5 Mg, Qw		Not Reported
	Xeljanz			C		5 Mg, Qod		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17307242	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013790			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Steatosis; Synovitis; Treatment Failure	Leflunomide			S	Unknown	Unk, Stop Date-??-Oct-2009		Sanofi
	Hydroxychloroquine			S	Unknown	Unk		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Actemra			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17307937	EXPEDITED (15-DAY)		OT	CA-SA-2020SA013792			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Hand Deformity; Joint Range Of Motion Decreased; Peripheral Swelling; Therapeutic Product Effect Decreased; White Blood Cell Count Decreased	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Hydroxychloroquine			S	Unknown	400 Mg		Sanofi
	Methotrexate			S	Unknown	17.5 Mg, Qw		Not Reported
	Actemra			S	Subcutaneous	162 Mg		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Mg		Not Reported
	Rituxan			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17309844	EXPEDITED (15-DAY)		OT	CA-ROCHE-2524259			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness;	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Solution		Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Depo-Medrol			C	Unknown	Suspension Intraarticular		Not Reported
	Diclofenac			C	Unknown			Not Reported
	Humira			C	Unknown	Solution Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain In Extremity; Peripheral Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Synovial Cyst; Tenosynovitis; Upper Respiratory Tract Infection	Hydroxychloroquine Sulfate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17519910	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020- 07738		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Etanercept			S	Subcutaneous	Unknown		Not Reported
	Cimzia			S	Subcutaneous	Unknown Single Use Pre- Filled Syringe, Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous	Unknown		Not Reported
	Humira			S	Subcutaneous	Unknown Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Xeljanz	C	Unknown	Unknown Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17597116	EXPEDITED (15-DAY)		HO, OT	JP-ADVANS PHARMA-GSH201903-000649			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis Bacterial; Gnathoschisis; Herpes Zoster; White Blood Cell Count Decreased	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia	
	Valixa			S	Oral	1800 Mg, Qd		Not Reported	
	Prograf			S	Oral	3 Mg, Qd		Not Reported	
	Prograf			S	Oral	2 Mg, Qd		Not Reported	
	Prograf			S	Oral	1.5 Mg, Qd		Not Reported	
	Prograf			S	Oral	2 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	6 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisolone	S	Oral	5 Mg, Qd	Not Reported
Bayaspirin	C		Unk	Not Reported
Rabeprazole Sodium	C		Unk	Not Reported
Rabeprazole Sodium	C			Not Reported
Halizon	C		Unk	Not Reported
Pitavastatin Calcium	C		Unk	Not Reported
Pitavastatin Calcium	C			Not Reported
Alendronate	C		Unk	Not Reported
Alendronate	C			Not Reported
Daiphen	C		Unk	Not Reported
Daiphen	C			Not Reported
Nitrazepam	C		Unk	Not Reported
Evoxac	C		Unk	Not Reported
Magnesium Oxide	C		Unk	Not Reported
Equa	C		Unk	Not Reported
Januvia	C		Unk	Not Reported
Humulin R	C		Unk	Not Reported
Aiphagan	C		Unk	Not Reported
Lumigan	C		Unk	Not Reported
Timoleate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17609185	EXPEDITED (15-DAY)		HO, LT, OT	CA-ADVANSZ PHARMA-GSH201702-001124			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Hydroxychloroquine			S	Oral	5 Mg/Kg, Qd		Concordia
Antibody Test Positive;	Hydroxychloroquine			S		Unk		Concordia
Arthritis; Arthritis; Arthritis;	Adalimumab			S	Unknown	Unknown		Not Reported
Arthropathy; Bone Density	Abatacept			S	Intravenous (not	250 Mg, Monthly		Not Reported
Decreased; C-Reactive					otherwise specified)			
Protein Increased;	Actemra			S	Intravenous (not	280 Mg, Qow		Not Reported
Condition Aggravated;								
Condition Aggravated;								



Detailed Report

Diarrhoea; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Drug Specific Antibody; Gastroenteritis Viral; Human Antichimeric Antibody Positive; Hypocalcaemia; Hypokalaemia; Hypotension; Immunodeficiency; Juvenile Idiopathic Arthritis; Liver Function Test Abnormal; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Nausea; Obesity; Pleural Effusion; Polyarthritis; Psoriasis; Pyrexia; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Short Stature; Synovitis; Therapy Non-Responder; Vomiting; Wheelchair User	Actemra	S	otherwise specified) Intravenous (not otherwise specified)	280 Mg, Weekly	Not Reported
	Anakinra	S	Subcutaneous	50 Mg, Qd	Not Reported
	Anakinra	S	Subcutaneous	Unk, 50	Not Reported
	Etanercept	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Etanercept	S	Subcutaneous	12.5 Mg, Weekly	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	70 G, Unk	Not Reported
	Immunoglobulins [Immunoglobulins Nos]	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	3 Mg/Kg, Weekly	Not Reported
	Infliximab	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Mg/M2	Not Reported
	Methotrexate	S	Unknown	Unk, Weekly	Not Reported
	Naproxen	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	5 Mg, Bid	Not Reported
	Prednisone	S	Oral	3 Mg, Bid	Not Reported
	Prednisone	S	Unknown	1.3 Mg, Bid	Not Reported
	Sulfasalazine	S	Oral	250 Mg, Qd	Not Reported
	Sulfasalazine	S			Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Triamcinolone	S	Unknown	Unk	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	250 Mg, Unk	Not Reported
	Enbrel	S	Subcutaneous	25 Mg, Weekly	Not Reported
	Tocilizumab	S	Unknown	250 Mg, Qd	Not Reported
	Tocilizumab	S	Intravenous (not	280 Mg Qcy (Every 2	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Isoniazid;Rifampicin	S	otherwise specified)	Weel)	
		Intravenous (not	Unknown	Not Reported
		otherwise specified)		
Humira	S	Subcutaneous	Unk	Not Reported
Folic Acid	C			Not Reported
Triamcinolone Hexacetonide	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17614242	EXPEDITED (15-DAY)		HO, OT	BR-ADVANSZ PHARMA-202003002062			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety; Arthropathy; Calculus Bladder; Cholecystectomy; Decreased Immune Responsiveness; Emotional Disorder; Gait Disturbance; Herpes Virus Infection; Herpes Zoster; Off Label Use	Hydroxychloroquine			S	Oral	1 Dosage Form, Qd Coated Tablet		Concordia
	Hydroxychloroquine			S	Oral	Coated Tablet1 Dosage Form, Qd		Concordia
	Aradois			C		50 Mg		Not Reported
	Influenza			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17678136	EXPEDITED (15-DAY)		OT	JP-ADVANSZ PHARMA-202004002834			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Once A Day And 2 Tablets Once A Day, Alternately		Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17699692	EXPEDITED (15-DAY)		LT, OT	CH-PFIZER INC-2020161844		86 YR	Female	CHE

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Hypoglycaemia	Tazobac			S	Intravenous (not otherwise specified)	4.5 G, 3x/Day		Pfizer
	Tazobac			S	Intravenous (not otherwise specified)	2.5 G, Single		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single (In Total)		Not Reported
	Cymbalta			C	Oral	60 Mg, 1x/Day		Not Reported
	Nexium Mups [Esomeprazole Magnesium]			C	Oral	20 Mg, 1x/Day		Not Reported
	Calciparine			C	Subcutaneous	5000 Iu, 2x/Day		Not Reported
	Lantus			C	Subcutaneous	20 Iu		Not Reported
	Lantus			C	Subcutaneous	10 Iu, 1x/Day		Not Reported
	Prednisone			C	Oral	10 Mg, 1x/Day		Not Reported
	Pregabalin			C	Oral	25 Mg, 2x/Day		Not Reported
	Torsemide			C	Oral	5 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17765723	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500991		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Naproxen	C	Unknown	Not Reported
Atorvastatin	C		Not Reported
Bisoprolol	C		Not Reported
Digoxin	C		Not Reported
Folic Acid	C		Not Reported
Furosemide	C		Not Reported
Hydrochlorothiazide	C		Not Reported
Methotrexate	C		Not Reported
Nifedipine	C		Not Reported
Palafer	C		Not Reported
Pantoprazole	C		Not Reported
Plaquenil /00072602/	C		Not Reported
Prednisone	C		Not Reported
Synthroid	C		Not Reported
Toloxin /00017701/	C		Not Reported
Valsartan	C		Not Reported
Vitamin D3	C		Not Reported
Xarelto	C		Not Reported
Xeljanz	C		Not Reported
Zinc Citrate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17769484	EXPEDITED (15-DAY)		DE, HO, OT	FR-MYLANLABS-2020M1046097			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Discomfort;	Azithromycin			S	Unknown	Unk		Not Reported
Electrocardiogram Qt Prolonged; Intentional Product Misuse; Loss Of Consciousness; Off Label Use; Ventricular	Plaquenil /00072603/			S	Unknown	Unk		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Arrhythmia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17778085	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200505937		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Adverse Event; Alopecia; Bronchitis Chronic; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Neck Pain; Neck Surgery; Off Label Use; Rheumatoid Factor Positive; Spinal Column Injury; Surgical Failure; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Oral			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mobicox			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17806672	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517490		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hepatitis; Hypersensitivity; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Sulfasalazine
Anakinra

S
C Unknown

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17806681	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517483			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Contraindicated Product Administered; Drug Ineffective; Gait Inability; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Xeljanz			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Leflunomide			S	Endocervical			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S				Not Reported
	Arava			S	Unknown			Not Reported
	Certolizumab Pegol			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Rituxan			C				Not Reported
Prednisone			C				Not Reported	
Naproxen			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17806682	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517486			Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Tofacitinib			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17812673	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517494		55 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Synovitis	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine /00072603/			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil /00072602/			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17812678	EXPEDITED (15-DAY)		DS, HO	CA-JNJFOC-20200517499		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Condition Aggravated; Drug Ineffective; Haematemesis; Hepatotoxicity; Joint Swelling; Nausea; Platelet Count Increased; Vitamin D Decreased; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Rosuvastatin			C	Unknown			Not Reported	
	Betahistine			C	Unknown			Not Reported	
	Desoximetasone			C	Unknown			Not Reported	
	Vitamin C /00008001/			C	Unknown			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17817547	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201709-005382			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Pain;	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia	
	Arava			S	Oral	20 Mg		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg		Not Reported	
	Humira			S	Subcutaneous	20 Mg, Qd		Not Reported	
	Humira			S	Subcutaneous	Unk, Qd		Not Reported	

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Peripheral Swelling; Rheumatoid Arthritis	Methotrexate	S	Subcutaneous	20 Mg, Weekly	Not Reported
	Methotrexate	S	Subcutaneous	20 Mg	Not Reported
	Orencia	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	1 Dosage Form, Qd	Not Reported
	Sulfasalazine	S	Unknown	1000 Mg, Bid	Not Reported
	Xeljanz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17820785	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020202410		40 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Hydroxychloroquine			S	Oral	400 Mg, Daily		Not Reported	
	Methylprednisolone			C		40-80 Mg, Daily		Not Reported	
	Acetaminophen			C		1.2-1.8 G, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17831439	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-025875		77 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Injury; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Form, Once A Day		Aurobindo	
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17831822	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANSZ PHARMA-202005005605			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Condition Aggravated; Covid-19; Hypoxia; Lymphopenia; Off Label	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	400 Mg, Bid		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia	

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Use	Prednisone	S	Unknown	9 Mg, Qd	Not Reported
	Tacrolimus	S	Unknown	Unk	Not Reported
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Losartan	C		25 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17832244	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-202005005639			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Gastroenteritis; Hepatitis; Nausea	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia	
	Methotrexate			S	Unknown	20 Mg, Weekly		Not Reported	
	Enbrel			C	Unknown	50 Mg, Weekly		Not Reported	
	Humira			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17832458	EXPEDITED (15-DAY)		HO	CA-ROCHE-2603672		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Asthenia; Astigmatism; Balance Disorder; Blood Glucose Increased; Cataract; Dizziness; Fall; Fatigue; Feeling Hot; Gastric Disorder; Gastrointestinal Disorder; Head Discomfort; Headache; Hot Flush	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Belimumab			S	Intravenous (not otherwise specified)			Not Reported	
	Desoximetasone			S	Unknown			Not Reported	
	Fentanyl			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone Acetate			S	Unknown			Not Reported	
	Gravol			C				Not Reported	
	Neurontin			C				Not Reported	
	Neurontin			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17832699	EXPEDITED (15-DAY)		DS, OT	BE-ADVANSZ PHARMA-202005005612			Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Heart Rate Increased; Off Label Use; Vertigo	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia	
	Folic Acid			C		Unk		Not Reported	
	Paracetamol			C		Unk		Not Reported	
	Levorichter 30			C		Unk		Not Reported	
	Befact			C		Unk		Not Reported	
	C-Will			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17832750	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202005005787			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Systemic Lupus Erythematosus	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Dupixent			S	Unknown	Unk		Not Reported	
	Dupilumab Pre-Filled Syringe			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17832947	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-247719		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Exposure During Pregnancy; Foetal Death; Foetal Growth Restriction; Pre-Eclampsia	Hydroxychloroquine			S	Unknown	Unk		Sun	
	Methyldopa			S	Unknown	Unk		Sun	
	Nifedipine			S	Unknown	Unk		Sun	

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Prednisone			S	Unknown	Unk	Mutual			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833269	EXPEDITED (15-DAY)		OT	IL-TEVA-2020-IL-1242016		43 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia Areata; Drug Ineffective; Gastrointestinal Disorder; Retinal Injury	Methotrexate			S	Unknown	Up To Dose		Barr	
	Hydroxychloroquine			S	Unknown			Teva	
	Belimumab			S	Unknown			Not Reported	
	Triamcinolone			S	Intradermal			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Azathioprine			C	Unknown	Up To Dose		Not Reported	
	Warfarin			C	Unknown			Not Reported	
	Aspirin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833476	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201711-006533			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia; Arthrodesis; Drug Ineffective; Joint Swelling; Knee Arthroplasty; Pain; Red Blood Cell Sedimentation Rate Abnormal; Shoulder Arthroplasty; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	Unk		Concordia	
	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Actemra			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	

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Kineret	S	Subcutaneous	Unk	Not Reported
Orencia	S	Unknown	Unk	Not Reported
Orencia	S		Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Oral	Unk	Not Reported
Anakinra	S	Unknown	100 Mg, Unk	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Desoximetasone	C		Unk	Not Reported
Methotrexate	C		Unk	Not Reported
Prednisone	C			Not Reported
Cortisone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833488	EXPEDITED (15-DAY)		DS	CA-ROCHE-2601407		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Subcutaneous			Not Reported
Alopecia; Anti-Cyclic	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 365		Not Reported
Citrullinated Peptide								
Antibody Positive;	Apo Hydroxyquine			S	Unknown			Not Reported
Arthropathy; Condition	Apo-Prednisone			S	Unknown			Not Reported
Aggravated; Discomfort;	Apo-Folic			S	Unknown			Not Reported
Drug Ineffective; Drug	Arava			S	Oral			Not Reported
Intolerance; Duodenal	Arava			S	Oral			Not Reported
Ulcer Perforation; Fatigue;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Glossodynia; Hand	Cetirizine Hydrochloride			S	Unknown			Not Reported
Deformity; Helicobacter	Cetirizine			S	Unknown			Not Reported
Infection; Hepatic Enzyme	Hydrochloride;Pseudoephedrine							
Increased; Hip	Hydrochloride							
Arthroplasty;								
Hypersensitivity; Infusion								
Related Reaction;								
Intentional Product Use								
Issue; Joint Swelling;								

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Knee Arthroplasty; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Pericarditis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Treatment Failure; Wound	Cimzia	S	Subcutaneous	Not Reported
	Cortisone	S	Oral	Not Reported
	Cortisone Acetate	S	Oral	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Unknown	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Desoximetasone	S	Cutaneous	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Oral	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Intra-arterial	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate Sodium	S	Oral	Not Reported
	Orencia	S	Subcutaneous	Not Reported

Therapy Duration: 11.0
Years

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Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 11.0 Months	Not Reported
Paracetamol	S	Unknown		Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Sarilumab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Stelara	S	Unknown		Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfasalazine	S	Oral	Therapy Duration: 365	Not Reported
Sulfasalazine	S	Oral		Not Reported
Sulfathalidine	S	Subcutaneous		Not Reported
Sulfathalidine	S			Not Reported
Topicort [Desoximetasone]	S	Oral		Not Reported
Topicort [Desoximetasone]	S	Unknown		Not Reported
Topicort [Desoximetasone]	S	Subcutaneous		Not Reported
Xeljanz	S	Unknown		Not Reported
Xeljanz	S	Unknown		Not Reported
Acetaminophen	C			Not Reported
Salazopyrin	C			Not Reported

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Tofacitinib Citrate				C				Not Reported	
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28-May-2020	17833501	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605476			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Off Label Use; Rheumatoid Arthritis; Therapeutic Response Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Xeljanz			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833562	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605159		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Joint Swelling; Pulmonary Mass	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Calcium Carbonate			C				Not Reported	
	Cetirizine			C				Not Reported	
	Cranberry [Vaccinium Spp.]			C	Unknown			Not Reported	
	Acetylsalicylic Acid			C	Unknown			Not Reported	
	Olopatadine			C				Not Reported	
	Prednisone			C				Not Reported	

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Quinapril Hydrochloride	C							Not Reported
Sandoz Rabeprazole	C	Unknown						Not Reported
Singulair	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833589	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202005005717			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Off Label Use	Hydroxychloroquine			S		Unk		Concordia
	Azithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833726	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001640			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Pre-Eclampsia	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Prednisone			S	Unknown	Unk		Not Reported
	Nifedipine			S	Unknown	Unk		Not Reported
	Methyldopa			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833823	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600694		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Iron Abnormal; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Disease Progression; Drug Hypersensitivity; Drug Ineffective; Drug	Actemra			S	Unknown	Therapy Duration 6.0 Years		Not Reported
	Rituximab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance;	Apo-Azathioprine	S	Unknown	Not Reported
Hypersensitivity;	Arava	S	Oral	Not Reported
Laryngeal Disorder;	Azathioprine	S	Unknown	Not Reported
Nausea; Off Label Use;	Ciclosporin	S	Unknown	Not Reported
Product Use Issue;	Ciclosporin	S	Oral	Not Reported
Pruritus; Psoriatic	Cimzia	S	Subcutaneous	Not Reported
Arthropathy; Rash;	Enbrel	S	Unknown	Not Reported
Rheumatoid Arthritis;	Gold	S	Unknown	Not Reported
Sciatica; Sinusitis;	Humira	S	Subcutaneous	Not Reported
Stomatitis; Therapeutic	Hydroxychloroquine	S	Unknown	Not Reported
Product Effect Incomplete;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Treatment Failure; Weight	Imuran [Azathioprine]	S	Unknown	Not Reported
Decreased	Infliximab	S	Intravenous (not otherwise specified)	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Varicella Zoster Vaccine Live	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Lyrica	S	Unknown	Not Reported
	Certolizumab Pegol	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Leflunomide	S	Unknown	Not Reported
Prednisone	C		Not Reported
Piroxicam	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833843	EXPEDITED (15-DAY)		OT	CA-ROCHE-2601050			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthropathy; Bone Disorder; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Finger Deformity; Off Label Use; Pain; Peripheral Swelling; Rash; Swelling; Tendon Disorder; Tenosynovitis; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Gold			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Codeine			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Penicillin G Sodium			S	Unknown			Not Reported
	Penicillin V Potassium			S	Unknown			Not Reported
	Rocuronium			S	Unknown			Not Reported
	Rocuronium Bromide			S	Unknown			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Prednisone			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17833947	EXPEDITED (15-DAY)		HO, OT	US-ADVANSZ PHARMA-202005005760			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest; Diarrhoea; Electrocardiogram Qt Prolonged; Hypoglycaemia; Product Use In Unapproved Indication	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834028	EXPEDITED (15-DAY)		DE, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US-001722			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Hydroxychloroquine			S	Transplacental	Unk		Ipca	
	Prednisone			S	Transplacental	Unk		Not Reported	
	Nifedipine			S	Transplacental	Unk		Not Reported	
	Methyldopa			S	Transplacental	Unk		Not Reported	
	Azathioprine			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834089	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-248216		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enoxaparina (2482a)	S	Subcutaneous	40 Milligram, Daily	Not Reported
Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg ; In Total	Not Reported
Dexketoprofeno (7312a)	S	Intravenous (not otherwise specified)	25 Milligram, Tid	Not Reported
Hidroxicloroquina (2143a)	S	Oral	400 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834116	EXPEDITED (15-DAY)		HO, OT	ES-SA-2020SA133267		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Off Label Use; Thrombocytopenia	Hydroxychloroquine			S	Oral	400 Mg Day		Sanofi
	Hydroxychloroquine			S				Sanofi
	Azithromycin			S	Oral	500 Mg Day		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	80 Mg, Every 12 Hours		Sanofi
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg, 24h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834159	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606952			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834691	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02479		14 DAY	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Lymphopenia	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Tacrolimus			S	Transplacental	Unk		Not Reported
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834700	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608271			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Joint Swelling; Mobility Decreased; Osteomyelitis	Rituximab			S	Intravenous drip			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Acetaminophen			C				Not Reported
	Hydrocortisone Valerate			C				Not Reported
	Hydromorphone Hydrochloride			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	C	Not Reported
	Lyderm [Fluocinonide]	C	Not Reported
	Naproxen	C	Not Reported
	Prednisone	C	Not Reported
	Sodium Aurothiomalate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834701	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201612-006568			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Fatigue; Gait Disturbance; Incorrect Dosage Administered; Influenza Like Illness; Malaise; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Walking Aid User	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Bid		Not Reported
	Methotrexate Sodium			S	Subcutaneous	20 Mg, Weekly		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	5 Mg, Qd		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Infliximab			S	Oral	300 Mg, Qd		Not Reported
	Pantoloc			C		Unk		Not Reported
	Atorvastatin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834702	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201710-005674			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated;	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Bid		Concordia

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug	Hydroxychloroquine	S	Unknown	200 Mg, Bid, Tablet	Concordia
Ineffective; Drug	Hydroxychloroquine	S	Unknown	200 Mg, Bid	Concordia
Ineffective; Drug	Arava	S	Oral	20 Mg, Qd	Not Reported
Ineffective; Drug	Paracetamol	S	Unknown	325 Mg	Not Reported
Ineffective; Drug	Actemra	S	Unknown	Unk	Not Reported
Ineffective; Drug	Enbrel	S	Unknown	50 Mg, Weekly	Not Reported
Ineffective; Drug	Cimzia	S	Subcutaneous	Unk	Not Reported
Ineffective; Drug	Humira	S	Subcutaneous	Unk	Not Reported
Intolerance; Fatigue; Gait	Orencia	S	Unknown	Unk	Not Reported
Disturbance; Joint	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Swelling; Loss Of	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Personal Independence In	Simponi	S	Subcutaneous	Unk	Not Reported
Daily Activities; Malaise;	Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Nephrolithiasis; Pain; Pain	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
In Extremity; Peripheral	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
Swelling; Red Blood Cell	Apo-Acetaminophen	S	Unknown	Unk Unk, Prn	Not Reported
Sedimentation Rate	Tylenol	S	Unknown		Not Reported
Increased; Rheumatoid	Acetaminophen,	S	Unknown	Unk	Not Reported
Arthritis; Somnolence;	Diphenhydramine Hydrochloride				
Somnolence; Visual	Tylenol	C		Unk	Not Reported
Impairment	Codeine Phosphate	C			Not Reported
	Meloxicam	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Synthroid	C			Not Reported
	Celebrex	C		Unk	Not Reported
	Hydromorph	C			Not Reported
	Leflunomide	C		Unk	Not Reported
	Acetaminophen, Codeine	C			Not Reported
	Phosphate				
	Hydromorphone Hcl	C			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834708	EXPEDITED (15-DAY)		OT	JP-ADVANSZ PHARMA-GSH201903-000662			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Ocular Hypertension	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia
	Prednisolone			S	Unknown	Unknown		Not Reported
	Prednisolone			C		6 Mg, Qd		Not Reported
	Prednisolone			C		Unk		Not Reported
	Prograf			C		Unk		Not Reported
	Actonel			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834709	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA-GSH201702-001198			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Hormone Level Abnormal; Immobile; Intentional Product Misuse; Loss Of Personal Independence In Daily Activities; Menopausal Symptoms; Menopause; Mobility Decreased; Musculoskeletal Stiffness; Pain; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qd		Concordia
	Hydroxychloroquine			S	Oral	Unk, Qd		Concordia
	Leflunomide			S	Oral	20 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Not Reported
	Methotrexate Sodium			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Failure	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	1 Dosage Form, Weekly (50)	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Mefenamic Acid	S		400 Mg, Bid	Not Reported
	Mefenamic Acid	S		2 Dosage Form, Qd	Not Reported
	Mefenamic Acid	S		2 Dosage Form, Qd	Not Reported
	Arava	S	Unknown	20 Mg, Qd	Not Reported
	Sulfasalazine	C		Unk	Not Reported
	Advil	C	Unknown	400 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834731	EXPEDITED (15-DAY)		DS, OT	CA-ADVANSZ PHARMA-GSH201811-003897			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Application Site Pain; Arthritis; Arthropathy; C-Reactive Protein Increased;	Hydroxychloroquine Sulfate (Authorized Generic), Plaquenil			S	Unknown	Unk		Concordia
Contraindicated Product Administered; Deformity; Disability; Drug Ineffective; General Physical Health Deterioration; Infusion Related Reaction; Infusion Site Reaction; Joint Destruction; Joint Effusion; Juvenile Idiopathic Arthritis; Mean Cell Haemoglobin Decreased; Mean Cell Volume Decreased; Mean Platelet	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	15 Mg/M2, Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	Unk		Not Reported
	Abatacept			S				Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Tocilizumab			S				Not Reported
	Etanercept			S	Unknown	15 Mg, Freq: Unk X 1 Weeks		Not Reported
	Adalimumab			S	Subcutaneous	40 Mg, Weekly		Not Reported
	Rituximab			S	Intravenous (not	420 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Volume Decreased; Monocyte Count Increased; Musculoskeletal Deformity; Osteoarthritis; Physical Disability; Platelet Count Increased; Red Blood Cell Sedimentation Rate; Red Cell Distribution Width Decreased; Treatment Failure; Vascular Access Complication; White Blood Cell Count Increased	Infliximab	S	otherwise specified) Unknown	200 Mg, Weekly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17834768	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605290			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Nausea; Off Label Use; Oral Discomfort; Uveitis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xeljanz	S	Unknown	Not Reported
	Prednisone	C		Not Reported
	Cimzia	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607444		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypersensitivity; Psoriatic Arthropathy; Synovitis	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Cosentyx			S	Subcutaneous			Not Reported
	Apremilast			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Otezla			S	Unknown			Not Reported
	Otezla			S	Oral			Not Reported
	Infliximab			C				Not Reported
	Benzylpenicillin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835046	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- GSH201702-001115			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alanine Aminotransferase Increased; Arthritis; Condition Aggravated; Drug Ineffective; Drug Ineffective; Drug Ineffective; Menopausal Symptoms; Musculoskeletal Stiffness; Rheumatoid Arthritis; Swelling; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Hydroxychloroquine Sulfate (Authorized Generic), Plaquenil	S	Oral	400 Mg, Qd	Concordia
	Leflunomide	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate	S	Oral	10 Mg, Weekly	Not Reported
	Methotrexate	S	Oral	20 Mg, Weekly	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	1 Dosage Form, Unk	Not Reported
	Advil	S	Unknown	400 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Unknown	5 Mg, Bid	Not Reported
	Mefenamic Acid	S		400 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835058	EXPEDITED (15-DAY)		OT	CA-ROCHE-2602950			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous drip	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835073	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204798		65 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Fibrin D Dimer Increased; Gastrointestinal Haemorrhage; Haematochezia; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 2x/Day		Not Reported
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Oseltamivir [Oseltamivir Phosphate]			C		Unk Unk, 2x/Day		Not Reported
	Ceftriaxone			C		Unk		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported
	Clexane			C	Subcutaneous	80 Mg, 2x/Day		Not Reported
	Amiodarone Hcl			C	Intravenous (not otherwise specified)	900 Mg, As Needed		Not Reported

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Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Ug, As Needed	Not Reported
Noradrenaline [Norepinephrine]	C	Intravenous (not otherwise specified)	16 Mg, As Needed	Not Reported
Lactulona	C	Oropharingeal	20 MI, 3x/Day	Not Reported
Lasix [Furosemide]	C	Intravenous (not otherwise specified)	20 Mg, As Needed	Not Reported
Luftal Max	C	Oropharingeal	40 Drop, 3x/Day	Not Reported
Nexium [Esomeprazole Magnesium]	C	Oropharingeal	20 Mg, 1x/Day	Not Reported
Nujol	C	Oropharingeal	20 MI, 3x/Day	Not Reported
Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835077	EXPEDITED (15-DAY)		OT	ES-ACCORD-183570		60 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Gastrointestinal Pain; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported
	Kaletra			S	Oral	Strength-200/50 Mg		Not Reported
	Omeprazole			C	Oral			Not Reported
	Paracetamol			C	Oral	Strength-1,000 Mg 40 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835078	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-183327		90 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported
	Ceftriaxone			S	Intravenous (not	2 Gr		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine	S	otherwise specified)	Sedation	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835083	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528684			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Head Injury; Road Traffic Accident	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835087	EXPEDITED (15-DAY)		CA, HO, OT	CA-JNJFOC-20200528676			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anaemia Of Chronic Disease; Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Escherichia Urinary Tract Infection; Fungal Infection; Haemodilution; Headache; Hepatic Cyst; Hepatic Haematoma; Interferon Gamma Release Assay Positive; Joint Swelling;	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lymphadenopathy; Microcytic Anaemia; Mouth Ulceration; Musculoskeletal Stiffness; Neutropenia; Pulmonary Fibrosis; Pulmonary Mass; Pyrexia; Renal Cyst; Thalassaemia	Isoniazid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835088	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528681			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Lymphoma	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Desoximetasone			C	Unknown			Not Reported
	Diclofenac			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835089	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528679			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835091	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528675		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835105	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528683		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Dyspepsia; Hepatic Enzyme Increased; Hypertension; Pneumonia; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Sulfasalazine			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835134	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200528667			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Contraindicated Product Administered; Fatigue; Glossodynia; Pemphigus; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Simponi			S	Subcutaneous			Janssen
	Simponi			S	Subcutaneous			Janssen
	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Desoximetasone	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Folic Acid	S	Unknown	Not Reported
Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine /00884302/	S	Unknown	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835140	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020205698		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835335	EXPEDITED (15-DAY)		HO, OT	IT-ACCORD-183181		27 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Covid-19	Mycophenolic Acid			S				Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Prednisone/Prednisone Acetate			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835346	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020208547		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Rocephine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835384	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020208562		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Off Label Use; Product Use In Unapproved Indication; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Enoxaparin			S	Subcutaneous	80 Mg, 2x/Day (Every 12 Hours)		Not Reported	
	Hydroxychloroquine			S	Oral	400 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606654		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Pain; Peripheral Swelling; Rash; Swelling; Treatment Failure; Urticaria	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Codeine			S	Unknown			Not Reported	

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Gold	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Rocuronium Bromide	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835500	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3420872-00			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Symptom; Heart Rate Irregular; Malaise; Weight Decreased	Rinvoq			S	Oral				Not Reported
	Plaquenil			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835715	EXPEDITED (15-DAY)		HO, OT	CA-ADVANSZ PHARMA-MAPI_00010560			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Interstitial Lung Disease; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Therapeutic	Hydroxychloroquine			S	Unknown	Unk			Concordia
	Leflunomide			S	Unknown	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown	Unknown			Not Reported

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Product Effect Decreased; Treatment Failure	Actemra	S	Unknown	Unknown	Not Reported
	Kineret	S	Unknown	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unknown, Powderfor Solution Intravenous	Not Reported
	Cimzia	S	Subcutaneous	Unknown	Not Reported
	Simponi	S	Subcutaneous	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Cellcept	S	Unknown	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unknown, Powder For Solution Intravenous	Not Reported
	Enbrel	S	Subcutaneous	Unknown	Not Reported
	Anakinra	S	Unknown	Unknown	Not Reported
	Gold	S	Unknown	Unknown	Not Reported
	Celebrex	C		Unk	Not Reported
	Methotrexate	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Humira	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835815	EXPEDITED (15-DAY)		OT	CA-ADVANSZ PHARMA- GSH201711-006254			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	200 Mg, Bid		Concordia
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50 Mg, Weekly		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported

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Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	Unk	Not Reported
	Paracetamol	S	Unknown	Unk	Not Reported
	Paracetamol	S	Unknown	325 Mg, Tablet	Not Reported
	Meloxicam	C		Unk	Not Reported
	Methotrexate	C		25 Mg/MI	Not Reported
	Synthroid	C		Unk	Not Reported
	Tylenol	C			Not Reported
	Acetaminophen And Codeine Phosphate	C			Not Reported
	Leflunomide	C		Unk	Not Reported
	Celebrex	C		Unk	Not Reported
	Hydromorphone Hcl	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17836106	NON-EXPEDITED			US-PFIZER INC-2020207847		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17836374	EXPEDITED (15-DAY)		HO, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000409			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Off Label Use; Ventricular	Furosemide			S	Oral	Unk		Validus	

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Fibrillation	Plaquenil /00072603/	S	Oral	Unk	Not Reported
	Plaquenil /00072603/	S			Not Reported
	Risordan /07346501/	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Irbesartan	S	Oral	Unk	Not Reported
	Carvedilol	S	Oral	Unk	Not Reported
	Azithromycin	S	Oral	250 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17836411	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200532831		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Product Use Issue; Rash; Rash Pruritic; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Myochrysine			S	Subcutaneous	Also Reported As Intramuscular		Not Reported
	Orencia			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Ciclosporin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

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28-May-2020	17837105	EXPEDITED (15-DAY)		DE, OT	ES-MYLANLABS-2020M1051992		86 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide;	Azithromycin			S		Unk		Not Reported	
Depressed Mood;	Hidroxicloroquina /00072601/			S		Unk		Mylan	
Hypertransaminaemia;	Kaletra			S	Unknown	Unk		Mylan	
Long Qt Syndrome	Metilprednisolona /00049601/			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17837148	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020208538		90 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
Electrocardiogram Qt	Plaquenil [Hydroxychloroquine			S	Oral	600 Mg, 1x/Day		Not Reported	
Prolonged; Off Label Use;	Sulfate]								
Product Use In	Tavanic			S	Oral	1000 Mg, 1x/Day		Not Reported	
Unapproved Indication									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17837483	EXPEDITED (15-DAY)		DS, HO	CA-JNJFOC-20200526841		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase	Remicade			S	Intravenous (not			Janssen	
Increased; Aspartate					otherwise specified)				
Aminotransferase	Simponi			S	Subcutaneous			Janssen	
Increased; Basal Cell	Stelara			S	Subcutaneous			Janssen	
Carcinoma; Blood	Ibuprofen			S	Oral			Johnson And Johnson	
Parathyroid Hormone	Ibuprofen			S	Oral			Johnson And Johnson	
Decreased; C-Reactive	Ibuprofen			S	Oral			Johnson And Johnson	
Protein Abnormal; C-									
Reactive Protein	Alendronate Sodium			S	Unknown			Not Reported	
Increased; Drug Eruption;									
Drug Hypersensitivity;									

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Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma	Apo-Ibuprofen	S	Oral	Not Reported
Skin; Headache; Hypercalcaemia; Inflammation; Infusion	Apo-Ibuprofen	S	Oral	Not Reported
Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Leflunomide	S	Oral	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S	Unknown	Not Reported
	Apremilast	S		Not Reported
	Ciclosporin	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S		Not Reported
	Enbrel	S		Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S		Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Enbrel	S		Not Reported
	Infliximab	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Orencia	S		Not Reported
	Otezla	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported

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Sulfasalazine	S	Endocervical	Not Reported
Tocilizumab	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Benadryl /00000402/	C	Unknown	Not Reported
Colchicine	C	Oral	Not Reported
Dexilant	C	Unknown	Not Reported
Febuxostat	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Gravol	C	Unknown	Not Reported
Mogadon	C	Oral	Not Reported
Nitrazepam	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Uloric	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

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28-May-2020	17837485	EXPEDITED (15-DAY)		HO	CA-JNJFOC-20200526864		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Alendronic Acid			S	Unknown			Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported

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Personal Independence In Daily Activities;	Leflunomide	S	Oral	Not Reported
Panniculitis; Peripheral Swelling; Rash; Rash	Methotrexate	S	Subcutaneous	Not Reported
Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17837487	EXPEDITED (15-DAY)	HO		CA-JNJFOC-20200526760		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma Skin; Hypercalcaemia;	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Alendronic Acid			S	Unknown			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	

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Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities;	Humira	S	Subcutaneous	Not Reported
Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	11290381	EXPEDITED (15-DAY)		OT	CA-ROCHE-1610671		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia; Arthritis; Blood Cholesterol Increased; C-Reactive Protein Abnormal; C- Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Drug	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Therapy Duration: 5 Years		Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 3 Years, Solution Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia; Herpes Zoster; Infection; Joint Swelling; Leukopenia; Liver Function Test Abnormal; Off Label Use; Oral Pain; Peripheral Swelling; Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis; Swelling; Synovitis; Tenderness; Therapeutic Product Effect Incomplete; Therapeutic Product Effect Incomplete	Enbrel	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 3 Years	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 1 Year	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Unknown	Therapy Duration: 9 Years	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year	Not Reported
	Arava	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Intramuscular		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	11.0 Years	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Vaginal		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Ativan	C	Unknown		Not Reported
	Cortisone	C	Intramuscular		Not Reported
	Cortisone	C	Intra-articular		Not Reported
	Cortisone	C	Oral		Not Reported
	Darifenacin	C	Unknown	As Required	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C	Unknown	As Required	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	C	Unknown		Not Reported
Loperamide	C	Unknown		Not Reported
Norflex [Orphenadrine Citrate]	C	Unknown		Not Reported
Omnaris	C	Unknown	Spray, Metered Dose	Not Reported
Pantoprazole Sodium	C			Not Reported
Synthroid	C			Not Reported
Vagifem	C	Unknown	Vaginal Tablet	Not Reported
Anakinra	C			Not Reported
Abatacept	C			Not Reported
Leflunomide	C	Unknown		Not Reported
Lasix [Furosemide]	C	Unknown		Not Reported
Dyclonine Hydrochloride	C			Not Reported
Enablex [Darifenacin Hydrobromide]	C	Unknown	Tablet (Extended Release)	Not Reported
Pantoloc [Pantoprazole]	C	Unknown	Tablet (Enteric Coated)	Not Reported
Urispas	C	Unknown		Not Reported
Triamcinolone Acetonide	C	Intra-articular		Not Reported
Trimethoprim	C	Unknown		Not Reported
Restasis	C	Unknown		Not Reported
Plantago Ovata	C	Unknown		Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown		Not Reported
Pantoprazole	C			Not Reported
Oxyneo	C	Unknown		Not Reported
Orphenadrine Hydrochloride	C	Unknown	1.0 Dosage Forms	Not Reported
Morphine Sulfate	C	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	C	Intra-articular		Not Reported
Kineret	C	Unknown		Not Reported
Kadian	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Dyclone	C			Not Reported
Desoximetasone	C	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Desoximetasone	C	Unknown	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Diphenhydramine	C		Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Codeine	C		Not Reported
Acetaminophen	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	11379748	EXPEDITED (15-DAY)		OT	CA-ROCHE-1620025		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Back Disorder; Condition Aggravated; Contraindicated Product Administered; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Infiltration Anaesthesia; Mouth Ulceration; Off Label Use; Oral Mucosal Exfoliation; Osteoarthritis; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis; Synovitis; Treatment Failure; Vasculitic Rash	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 1 Year		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported
	Prednisone			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorph Contin	C	Not Reported
Dilaudid	C	Not Reported
Amlodipine	C	Not Reported
Eletriptan	C	Not Reported
Cimzia	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	12082828	EXPEDITED (15-DAY)		OT	CA-ROCHE-1712228			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Joint Swelling; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)	4-8mg/Kg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral	Adequate Trial Of 3months In 2010		Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 195 Days Form Of Admin Text: Solution Subcutaneous		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral	Therapy Duration: 6 Years		Not Reported
	Methotrexate			S	Intramuscular	Therapy Duration: 6 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Therapy Duration: 6 Years		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Naproxen Sodium	S	Unknown	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Lantus	C	Subcutaneous	Solution
Lozide [Indapamide]	C		Not Reported
Prednisone	C		Not Reported
Ramipril	C		Not Reported
Ergocalciferol	C		Not Reported
Vitamin D3	C		Not Reported
Xeljanz	C	Oral	Not Reported
Calcium	C		Not Reported
Metformin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	13251082	EXPEDITED (15-DAY)		OT	CA-ROCHE-1895049		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Condition Aggravated; Drug Ineffective; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 4.0 Month(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Winpred	S	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	13266498	EXPEDITED (15-DAY)		OT	CA-BAXTER-2017BAX007297		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Infection; International Normalised Ratio Fluctuation; Therapeutic Product Effect Incomplete	Metronidazole Injection, Usp			S	Unknown	Dosage Form: Not Specified		Baxter
	Metronidazole Injection, Usp			S	Intravenous (not otherwise specified)	Dosage Form: Liquid Intravenous		Baxter
	Arava			S	Unknown	Tablet		Not Reported
	Arthrotec			S	Unknown			Not Reported
	Bisoprolol			S	Unknown	Dosage Form: Tablet		Not Reported
	Bisoprolol Fumarate			S	Unknown	Tablet		Not Reported
	Ceclor			S	Unknown	Dosage Form Not Specified		Not Reported
	Celebrex			S	Oral			Not Reported
	Celebrex			S	Oral	Dosage Form: Capsules		Not Reported
	Demerol			S	Unknown	Dosage Form Not Specified		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythromycin Estolate	S	Unknown	Dosage Form Not Specified	Not Reported
Erythromycin	S	Unknown	Dosage Form Not Specified	Not Reported
Humira	S	Unknown	Solution Subcutaneous	Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Leflunomide	S	Unknown		Not Reported
Levofloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
Levofloxacin	S	Unknown		Not Reported
Lyrica	S	Unknown		Not Reported
Meperidine Hydrochloride	S	Unknown		Not Reported
Methotrexate Sodium	S	Unknown		Not Reported
Norfloxacin	S	Unknown	Dosage Form Not Specified	Not Reported
Plaquenil	S	Unknown	Tablet	Not Reported
Plaquenil	S	Oral	Tablet	Not Reported
Prednisone	S	Unknown	Dosage Form Not Specified	Not Reported
Sulfasalazine	S	Unknown	Dosage Form Not Specified	Not Reported
Erythro Base	S	Unknown	Dosage Form: Tablet	Not Reported
Methotrexate	S	Unknown	Dosage Form: Not Specified	Not Reported
Levofloxacin Hemihydrate	S	Unknown		Not Reported
Cefaclor	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Celecoxib	S	Oral	200 Mg, Qd	Not Reported
Meperidine	S	Unknown	Dosage Form: Not Specified	Not Reported
Apo-Leflunomide	S	Unknown	Dosage Form: Tablet	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	13266763	EXPEDITED (15-DAY)		OT	CA-ROCHE-1897125			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anti-Cyclic Citrullinated Peptide Antibody Positive; Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Stomatitis; Weight Decreased	Rituxan			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Champix			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Valacyclovir [Valaciclovir]			C				Not Reported
	Vimovo			C				Not Reported
	Crestor			C				Not Reported
	Oxycocet			C	Oral			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	13932857	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2017AP017314		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell	Apo-Hydroxyquine			S	Unknown	Unk		Apotex
	Alendronate			S	Unknown	70 Mg, Q.Wk.		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Unk		Apotex
	Cyclosporine			S	Unknown	150 Mg, Qd		Apotex

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Carcinoma; Blood	Enbrel	S	Unknown	25 Mg, Q.O.Wk.	Not Reported
Parathyroid Hormone	Enbrel	S	Unknown	25 Mg, Unk	Not Reported
Decreased; C-Reactive	Enbrel	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
Protein Increased; Drug	Enbrel	S	Subcutaneous	25 Mg, Q.O.Wk.	Not Reported
Eruption; Drug	Humira	S	Unknown	40 Mg, Unk	Not Reported
Hypersensitivity; Drug	Humira	S	Subcutaneous	40 Mg, Q.O.Wk.	Not Reported
Ineffective; Drug	Humira	S	Subcutaneous	40 Mg, Q.Wk.	Not Reported
Tolerance Decreased;	Methotrexate	S	Unknown	12 Mg, Q.Wk.	Not Reported
Erythema; Granuloma	Methotrexate	S	Unknown	12.5 Mg, Unk	Not Reported
Skin; Hypercalcaemia;	Methotrexate	S	Unknown	12.5 Mg, Q.Wk.	Not Reported
Hypersensitivity;	Methotrexate	S	Oral	10 Mg, Q.Wk.	Not Reported
Inflammation; Infusion	Methotrexate	S	Unknown	10 Mg, Q.Wk.	Not Reported
Related Reaction; Loss Of	Methotrexate	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
Personal Independence In	Methotrexate	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Daily Activities; Off Label	Methotrexate	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Use; Panniculitis;	Methotrexate Sodium	S	Subcutaneous	17.5 Mg, Q.Wk.	Not Reported
Peripheral Swelling;	Methotrexate Sodium	S	Subcutaneous	15 Mg, Q.Wk.	Not Reported
Product Use Issue; Rash;	Methotrexate Sodium	S	Subcutaneous	10 Mg, Q.Wk.	Not Reported
Rash Pruritic; Rheumatoid	Orencia	S	Unknown	Unk, 275 (Unspecified Unit)	Not Reported
Arthritis; Rheumatoid	Orencia	S	Unknown	780 Mg, Q.Wk.	Not Reported
Nodule; Skin Necrosis;	Rituxan	S	Unknown	1000 Mg, Bid	Not Reported
Skin Ulcer	Sulfasalazine	S	Unknown	Unk	Not Reported
	Sulfasalazine	S	Unknown	680 Mg, 1 Every 4 Weeks	Not Reported
	Tocilizumab	S	Unknown	360 Mg, Q.M.T.	Not Reported
	Tocilizumab	S	Unknown	680 Mg, Q.M.T.	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Remicade	S	Unknown	Unk, 365 (Unspecified Unit)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
Actemra	S	Unknown	360 Mg, Q.M.T.	Not Reported
Actemra	S	Unknown	680 Mg, Unk	Not Reported
Actemra	S	Unknown	680 Mg, Unk, 1 Every 4 Week	Not Reported
Actemra	S	Unknown	360 Mg, Q.Wk.	Not Reported
Myochrysine	S	Unknown	50 Mg, Q.M.T.	Not Reported
Myochrysine	S	Intramuscular	50 Mg, Q.M.T.	Not Reported
Rituximab	S	Unknown	1000 Mg, Bid	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Fosamax	S	Unknown	70 Mg, Q.Wk.	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Ciclosporin	C	Unknown	150 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	13947306	EXPEDITED (15-DAY)		OT	CA-ROCHE-1875144		56 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein	Actemra			S	Unknown			Not Reported	
Abnormal; Drug	Oxycodone			S	Unknown			Not Reported	
Hypersensitivity; Drug	Marijuana			S	Unknown			Not Reported	
Ineffective; Drug	Enbrel			S	Unknown			Not Reported	
Intolerance; Feeling	Humira			S	Subcutaneous			Not Reported	
Abnormal; Haemoglobin	Methotrexate Sodium			S	Unknown			Not Reported	
Decreased; Herpes	Minocycline Hydrochloride			S	Unknown			Not Reported	
Zoster; Interstitial Lung	Orencia			S	Unknown			Not Reported	
Disease; Joint Swelling;									
Off Label Use;									
Photosensitivity Reaction;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Stomatitis; Urticaria	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Oxycodone Hydrochloride	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Lyrica	C	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Orencia	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	14299394	EXPEDITED (15-DAY)		OT	CA-ROCHE-2038238			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Operation; Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Rheumatoid Factor Positive; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown	Therapy Duration: 5 Years		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 6 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Therapy Duration: 2 Years		Not Reported
	Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Therapy Duration: 790 Nos	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Orencia	S	Unknown	Therapy Duration: 3 Years	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 8 Months	Not Reported
Anakinra	S	Unknown		Not Reported
Apo-Hydroxyquine	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Arava	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine Sulphate	S	Unknown		Not Reported
Sulfasalazine	C	Unknown		Not Reported
Wellbutrin	C	Oral	Extended Release	Not Reported
Xeljanz	C	Unknown		Not Reported
Bupropion	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	14549482	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006555			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankylosing Spondylitis;	Amitriptyline			S	Unknown	Unk		Apotex	
Arthritis; Chest Pain; Drug	Hydroxychloroquine			S	Unknown	Unk		Apotex	
Ineffective; Fibromyalgia;	Meloxicam			S	Unknown	Unk		Apotex	
Hla Marker Study Positive;	Plaquenil /00072602/			S	Unknown	Unk		Not Reported	
Immunodeficiency;	Mobicox			S	Unknown	Unk		Not Reported	
Kyphoscoliosis;									
Musculoskeletal									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Discomfort; Musculoskeletal Stiffness; Myofascial Pain	Enbrel	S	Unknown	500 Mg, Q.Wk.	Not Reported
Syndrome; Plantar	Humira	S	Subcutaneous	Unk	Not Reported
Fasciitis; Somnolence;	Sulfasalazine	S	Unknown	Unk	Not Reported
Spinal Osteoarthritis;	Folic Acid	C	Unknown	Unk	Not Reported
Therapeutic Product Effect	Methotrexate	C	Unknown	Unk	Not Reported
Incomplete	Naproxen	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	14815519	EXPEDITED (15-DAY)		OT	CA-ROCHE-2110721			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Reaction; Blood	Actemra			S	Unknown			Not Reported
Iron Abnormal;	Actemra			S	Unknown			Not Reported
Contraindicated Product	Arava			S	Oral			Not Reported
Administered; Diarrhoea;	Ciclosporin			S	Oral			Not Reported
Disease Progression;	Cimzia			S	Subcutaneous			Not Reported
Drug Hypersensitivity;	Enbrel			S	Unknown			Not Reported
Drug Ineffective; Drug	Enbrel			S	Unknown	Therapy Duration: 4.0		Not Reported
Intolerance;						Year(S)		
Hypersensitivity;	Humira			S	Subcutaneous			Not Reported
Laryngeal Disorder;	Humira			S	Unknown	Therapy Duration: 4.0		Not Reported
Nausea; Off Label Use;						Year(S)		
Product Use Issue;	Remicade			S	Intravenous (not	Therapy Duration: 2.0		Not Reported
Pruritus; Psoriatic					otherwise specified)	Year(S) Powder For		
Arthropathy; Rash;						Solution Intravenous		
Rheumatoid Arthritis;								
Sciatica; Sinusitis;	Methotrexate			S	Unknown			Not Reported
Stomatitis; Treatment	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported
Failure; Weight Decreased	Sulfate]							
	Sulfasalazine			S	Unknown			Not Reported
	Imuran [Azathioprine]			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Certolizumab Pegol	S	Unknown	Therapy Duration: 9.0 Month(S)	Not Reported
Gold	S	Unknown		Not Reported
Azathioprine	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Apo-Azathioprine	S	Unknown		Not Reported
Infliximab	S	Intravenous (not otherwise specified)		Not Reported
Lyrica	S	Unknown		Not Reported
Mycophenolate Mofetil	S	Unknown		Not Reported
Orencia	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Apo-Leflunomide	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Sodium Aurothiomalate	S	Unknown		Not Reported
Varicella Zoster Vaccine Live	S	Subcutaneous		Not Reported
Varicella Zoster Vaccine Live	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	15454776	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190744		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Arthralgia; Aspartate Aminotransferase Increased; Cardiac Murmur; Drug Intolerance; Dyspnoea Exertional; Fatigue; Hyperkeratosis;	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Interstitial Lung Disease; Joint Swelling; Osteoarthritis; Therapeutic Product Effect Decreased	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Asa	C	Unknown	Not Reported
	Clonazepam	C	Oral	Not Reported
	Desipramine	C	Unknown	Not Reported
	Gabapentin	C	Oral	Not Reported
	Nitroglycerin	C	Unknown	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	15612498	EXPEDITED (15-DAY)		OT	PHHY2018ES109862		22 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Oesophageal Candidiasis; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Prednisone			S	Unknown	2.70 G, Unk		Not Reported
	Hydroxychloroquine			S	Unknown			Novartis
	Hydroxychloroquine			S				Novartis
	Imurel			S	Unknown	Unknown Dose		Not Reported
	Imurel			S				Not Reported
	Imurel			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	15633947	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT156440		15 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Bronchitis; Chills; Cushingoid; Drug Ineffective;	Hydroxychloroquine			S	Oral	Unk		Novartis
	Hydroxychloroquine			S	Unknown	Unk		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastrointestinal Disorder; Haematuria; Headache; Hypertransaminasaemia; Lupus Nephritis; Meningitis Cryptococcal; Muscle Atrophy; Muscle Hypertrophy; Nausea; Off Label Use; Pneumonia; Proteinuria; Pyrexia	Mycophenolate Mofetil	S	Unknown	1 G, Qd	Not Reported
	Mycophenolate Mofetil	S			Not Reported
	Prednisone	S	Oral	1 Mg/Kg, Qd	Not Reported
	Prednisone	S			Not Reported
	Tacrolimus	S	Unknown	Unk	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	350 Mg, Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	375 Mg/M2, Unk	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	300 Mg, Unk	Not Reported
	Cyclophosphamide	S	Oral	1 Mg/Kg, Unk	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	300 Unk, 1x Pulse	Not Reported
	Cyclophosphamide	S	Intravenous (not otherwise specified)	500 Mg 1x Pulse Therapy	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	15734887	EXPEDITED (15-DAY)		OT	US-MYLANLABS- 2018M1091973			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Lymphopenia	Azathioprine			S	Transplacental			Not Reported
	Hydroxychloroquine			S	Transplacental			Not Reported
	Prednisone			S	Transplacental			Not Reported
	Tacrolimus			S	Transplacental			Not Reported
	Betamethasone			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	16257921	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-039626		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; Back Disorder; Drug Ineffective; Drug Intolerance; Mouth Ulceration; Vasculitic Rash	Orencia	S	Intravenous (not otherwise specified)	500 Milligram, Q4wk	Bristol Myers Squibb
	Actemra	S	Intravenous (not otherwise specified)	8 Milligram/Kilogram	Not Reported
	Anakinra	S	Unknown	100 Milligram, Qd	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine	S	Unknown	200 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Leflunomide	S	Oral	20 Milligram, Q2wk	Not Reported
	Methotrexate	S	Subcutaneous	20 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	12.5 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	16697274	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019344315			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Arthropathy; Ligament Sprain; Nasopharyngitis; Oedema Peripheral; Pain In Extremity; Paraesthesia; Peripheral Coldness; Pulmonary Hypertension; Therapeutic Product Effect Incomplete; Visual Impairment	Ramipril			S	Oral	1 Df, Bid (1 - 0 - 1)		Pfizer
	Ramipril			S	Unknown	5 Mg, Qd		Pfizer
	Apixaban			S	Unknown	2.5 Mg, Bid		Pfizer
	Apixaban			S	Unknown	2 Df, Qd		Pfizer
	Lyrica			S	Unknown	100 Mg, Tid		Pfizer
	Lyrica			S	Unknown	1 Df, Tid (1 Df, 3x/Day (1 - 1- 1))		Pfizer
	Pregabalin			S	Unknown	100 Mg, Tid		Pfizer
	Pregabalin			S	Unknown	1 Df, 3x/Day		Pfizer
	Omeprazole			S	Oral	1 Df, Bid (1 - 0 - 1)		Pfizer
	Omeprazole			S	Oral	20 Mg, Bid (40mg/Day)		Pfizer
	Sildenafil Citrate			S	Unknown	60 Mg, Qd		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quensyl	S	Unknown	40 Mg, Bid (80mg/Day)	Not Reported
Quensyl	S	Unknown	20 Mg, Bid (40 Mg/Day)	Not Reported
Volibris	S	Oral	30 Mg, Qd	Not Reported
Volibris	S	Oral	1 Df, Qd	Not Reported
Spasmolyt	S	Unknown	1 Df, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	30 Mg, Qd	Not Reported
Spasmolyt	S	Unknown	15 Mg, Qd	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw (Solution For Injection In Pre-Filled Syringe)	Not Reported
Roactemra	S	Subcutaneous	162 Mg, Qw	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Ambrisentan	S	Oral	1 Df, Qd	Not Reported
Ambrisentan	S		Unk	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Ambrisentan	S	Unknown	30 Mg, Qd	Not Reported
Ambrisentan	S	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	16872434	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2412613		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Actemra			S	Subcutaneous			Not Reported
Ankle Arthroplasty; Anti-	Rituxan			S	Intravenous (not	Cyclical		Not Reported
Cyclic Citrullinated Peptide					otherwise specified)			
Antibody Positive; Arthritis;	Rituxan			S	Intravenous (not			Not Reported
Arthropathy; Condition					otherwise specified)			
Aggravated;	Actemra			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Diarrhoea;	Actemra			S	Intravenous (not			Not Reported
Dizziness; Drug					otherwise specified)			
Hypersensitivity; Drug				S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Drug Intolerance; Foot Deformity; Foot Operation; Gastroenteritis Viral; Hand Deformity; Hypertension; Hypocalcaemia; Hypokalaemia; Hypotension; Ill-Defined Disorder;	Actemra	S	otherwise specified)	Not Reported
Immunodeficiency; Infection; Intentional Product Use Issue; Joint Destruction; Limb Discomfort; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise; Mobility Decreased; Nausea; Nodule; Obesity; Off Label Use; Pleural Effusion; Polyarthritis; Psoriasis; Pulmonary Fibrosis; Pyrexia; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid Factor Positive; Septic Shock; Synovitis; Therapeutic Product Effect Decreased; Therapy Non-Responder; Vomiting; Wheelchair User	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Subcutaneous	Not Reported
	Actemra	S	Unknown	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Anakinra	S	Subcutaneous	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported

**FDA Adverse Event Reporting System
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Detailed Report**

Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Subcutaneous	Not Reported
Actonel	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Apo-Leflunomide	S	Oral	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Gold	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Oral	Not Reported
Leflunomide	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Apo-Naproxen	S	Unknown	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Apo-Prednisone	S	Oral	Not Reported
Gammagard	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Naproxen	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Triamcinolone	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sodium Aurothiomalate	S	Subcutaneous	Not Reported
Risedronate Sodium	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Folic Acid	C		Not Reported
Risedronate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	16927061	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-096726		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Pressure Fluctuation; Body Height Decreased; Drug Ineffective; Drug Intolerance; Flushing; Inflammation; Intentional Product Use Issue; Interstitial Lung Disease; Irritable Bowel Syndrome; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Arava			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Qd		Not Reported
	Lyricea			S	Unknown	150 Milligram		Not Reported
	Sulfasalazin			S	Unknown	1000 Milligram, Bid		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	400 Milligram		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Simponi			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Acetaminophen			C	Unknown	3000 Milligram, Qd		Not Reported
	Esomeprazole			C	Unknown	40 Milligram, Qd		Not Reported
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported
	Bimatoprost			C	Ophthalmic	Unk Unk, Qd		Not Reported
	Pseudoephedrine Hydrochloride			C	Unknown	10 Milligram, Qd		Not Reported

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	Trazodone	C	Unknown	200 Milligram, Qd	Not Reported
	Valsartan	C	Unknown	Unk, Qd	Not Reported
	Wellbutrin	C	Unknown	300 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	16931807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2435261			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Grip Strength Decreased; Joint Swelling; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Mobicox			S	Oral			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17245909	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512661		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Bronchitis; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Colitis Microscopic; Contraindicated Product Administered; Diverticulitis; Drug Hypersensitivity; Drug	Actemra			S	Unknown	1.0 Dosage Forms		Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Cimzia			S				Not Reported
	Enbrel			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Drug	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Intolerance; Glaucoma;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hepatic Enzyme	Leflunomide	S	Unknown	Not Reported
Increased;	Orencia	S	Unknown	Not Reported
Hypersensitivity;	Orencia	S	Unknown	Not Reported
Hypertension; Intestinal	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported
Polyp; Joint Swelling;	Sulfate]	S	Unknown	Not Reported
Leukopenia; Memory	Sulfasalazine	S	Unknown	Not Reported
Impairment; Mobility	Sulfasalazine	S	Unknown	Not Reported
Decreased;	Xeljanz	S	Oral	Not Reported
Nephrolithiasis; Off Label	Apo-Leflunomide	S	Unknown	Not Reported
Use; Pneumonia; Product	Hydroxychloroquine	S	Oral	Not Reported
Dose Omission; Skin	Humira	S	Subcutaneous	Not Reported
Reaction; Synovitis;	Baclofen	C	Unknown	Not Reported
Therapeutic Product Effect	Baclofen	C	Unknown	Not Reported
Decreased; Therapeutic	Calcium	C	Unknown	Not Reported
Product Effect Incomplete;	Ergocalciferol	C	Unknown	Not Reported
Thyroid Disorder;	Estradiol	C	Unknown	Not Reported
Treatment Failure;	Furosemide	C	Unknown	Not Reported
Vomiting	Gravol	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Levaquin	C	Unknown	Not Reported
	Morphine	C	Unknown	Not Reported
	Zingiber Officinale	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Ophthalmic	Not Reported
	Acetaminophen	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Methotrexate	C	Unknown	Not Reported

1.0 Dosage Forms

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17281970	EXPEDITED (15-DAY)		OT	CA-ROCHE-2521190			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Diarrhoea; Drug Ineffective; Fibromyalgia; Gastroesophageal Reflux Disease; Ill-Defined Disorder; Pain; Skin Irritation; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Ibuprofen			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17299293	EXPEDITED (15-DAY)		OT	CA-ROCHE-2525016		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Density Decreased; Cataract; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Malaise; Mobility Decreased; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Pain; Pain In Extremity; Peripheral	Actemra			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Mobicox			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Depomedrol			C	Other			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling; Pulmonary Toxicity; Rash Maculo-Papular; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Lung; Synovial Cyst; Synovitis; Tenosynovitis; Viral Upper Respiratory Tract Infection	Depomedrol Diclofenac Pantoprazole Magnesium Plaquenil [Hydroxychloroquine Sulfate] Prednisone Xeljanz	C C C C C C	Other Unknown Unknown Unknown Unknown Oral	Suspension Intraarticular	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17376739	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533781		43 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Actonel			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17390927	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540924			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Contraindicated Product Administered; Drug Ineffective; Joint Swelling; Off Label Use; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17391235	EXPEDITED (15-DAY)		OT	CA-ROCHE-2536677		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Contraindicated Product Administered; Deformity; Drug Hypersensitivity; Drug	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Hepatotoxicity; Ill-Defined Disorder; Loss Of Consciousness; Malaise; Mobility Decreased; Musculoskeletal Disorder; Musculoskeletal Pain; Neck Pain; Off Label Use; Pain; Rheumatoid Arthritis; Syncope; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Anakinra	S	Unknown		Not Reported
	Arava	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Codeine	S	Unknown		Not Reported
	Codeine	S			Not Reported
	Enbrel	S	Subcutaneous	Therapy Duration: 5.0 Years	Not Reported
	Enbrel	S			Not Reported
	Humira	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 9.0 Years	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 15.0 Years	Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Adalimumab	C	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Prednisone	C	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17399182	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540688			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17464240	EXPEDITED (15-DAY)		HO	CA-ROCHE-2553935			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Nausea; Product Label Confusion; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			C				Not Reported
	Enbrel			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17472233	EXPEDITED (15-DAY)		HO	CA-ROCHE-2556500		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Amnesia; Drug Ineffective; Fatigue; Gastric Ulcer; Hallucination; Malaise; Oesophageal Disorder; Throat Cancer; Thrombosis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	6.0 Dosage Forms		Not Reported
	Tacrolimus			S	Unknown	5.0 Dosage Forms		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17558716	EXPEDITED (15-DAY)		OT	CA-ROCHE-2567123		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Inflammation; Joint Swelling; Muscle Spasms; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Urticaria	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Usp	Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Azathioprine	C			Not Reported
	Ciclosporin	C			Not Reported
	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C			Not Reported
	Actemra	C	Unknown		Not Reported
	Phenylbutazone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17580222	EXPEDITED (15-DAY)		OT	CA-BIOVITRUM-2020CA1336			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Contraindicated Product Administered; Drug Ineffective; Off Label Use	Kineret			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17614339	EXPEDITED (15-DAY)		DS	CA-ROCHE-2572169		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Breast Cancer Stage Iii; Depression; Diarrhoea; Disability; Drug Ineffective; Fine Motor Skill Dysfunction; Gait Disturbance; Gait Inability; Joint Range Of Motion Decreased; Memory Impairment; Mobility Decreased; Musculoskeletal Disorder; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Synovitis; Therapeutic Product Effect Decreased; Treatment Noncompliance	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17722293	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1227376		74 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coronavirus Infection; Off Label Use; Sinus Bradycardia	Azitromicina Teva 500 Mg			S	Oral	500 Mg		Not Reported
	Comprese Rivestite Con Film			S	Oral	400 Mg		Not Reported
	Plaquenil			C	Oral	10 Mg		Not Reported
	Stilnox 10 Mg Comprese							
	Rivestite Con Film							

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clexane T	C	Subcutaneous	8000 Ku	Not Reported
Lansoprazolo Teva Italia 30 Mg Capsule Rigide Gastroresistenti	C	Oral	30 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17722977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589713			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Enbrel			C	Subcutaneous			Not Reported
	Humira			C	Subcutaneous			Not Reported
	Orencia			C	Intravenous (not otherwise specified)			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17729388	EXPEDITED (15-DAY)		DS, OT	CA-JNJFOC-20200437131			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Celebrex	S		Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17740634	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP017728			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nephrolithiasis; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Hydroxychloroquine			S	Unknown	200 Mg, Bid		Apotex
	Acetaminophen			S	Unknown	325 Mg, Unk		Apotex
	Apo-Acetaminophen			S	Unknown	Unk		Apotex
	Apo-Leflunomide			S	Unknown	20 Mg, Qd		Apotex
	Plaquenil /00072602/			S	Unknown	200 Mg, Bid		Not Reported
	Enbrel			S	Unknown	50 Mg, Q.Wk. Therapy Duration 823 Unit Unspecified		Not Reported
	Enbrel			S	Unknown	50 Mg, Qd		Not Reported
	Enbrel			S	Unknown	40 Mg, Q.I.W		Not Reported
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Sulfasalazine	S	Oral	2000 Mg, Unk	Not Reported
Tylenol /00020001/	S	Unknown	Unk	Not Reported
Acetaminophen W/Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Acetaminophen With Codeine	C	Unknown	Unk	Not Reported
Meloxicam	C	Unknown	Unk	Not Reported
Synthroid	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	Unk, Q.Wk.	Not Reported
Acetaminophen And Codeine	C	Unknown	Unk	Not Reported
Celecoxib	C	Unknown	Unk	Not Reported
Hydromorphone Hcl	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17744167	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20200436843		77 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Alopecia; Arthritis Bacterial; Balance Disorder; Bladder Transitional Cell Carcinoma; Drug Ineffective; Drug Intolerance; Lymphoma; Nausea; Neoplasm Malignant; Neutropenia; Onychoclasia; Osteoarthritis; Synovitis; Tachycardia; Tooth Loss; Type 2 Diabetes Mellitus; White Blood Cell Count Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituxan	S	otherwise specified)	Not Reported
Sulfasalazine	S	Intravenous (not otherwise specified)	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Varicella Zoster Vaccine Live	S	Unknown	Not Reported
Desoximetasone	S	Intravenous (not otherwise specified)	Not Reported
Diclofenac	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17744168	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200436826			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Rheumatoid Arthritis; Rheumatoid Arthritis; Sciatica	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Methotrexate			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Caffeine			C	Unknown			Not Reported
	Codeine			C	Unknown			Not Reported
	Dorzolamide Hydrochloride			C				Not Reported
	Folic Acid			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meprobamate	C	Unknown	Not Reported
Phosphate /01053101/	C		Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported
Timolol Maleate	C	Ophthalmic	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17757965	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200500978		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Drug Ineffective; Rheumatoid Arthritis; Synovitis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S				Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17763317	EXPEDITED (15-DAY)		HO	CA-ROCHE-2594978		33 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Rituxan			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Condition			otherwise specified)	
Aggravated; Cough; Drug	Enbrel	S	Subcutaneous	Not Reported
Ineffective; Fatigue; Fine	Gold	S	Unknown	Not Reported
Motor Skill Dysfunction;	Hydroxychloroquine	S	Unknown	Not Reported
Goitre; Headache;	Methotrexate	S	Oral	Not Reported
Inflammation; Joint	Methotrexate Sodium	S	Unknown	Not Reported
Swelling; Knee	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Arthroplasty; Lower	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Respiratory Tract	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Infection; Musculoskeletal	Sulfasalazine	S	Unknown	Not Reported
Pain; Musculoskeletal	Apo-Prednisone	S	Oral	Not Reported
Stiffness; Nasopharyngitis;	Apo-Prednisone	S	Oral	Not Reported
Nephrolithiasis; Pain; Pain	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
In Extremity; Peripheral	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Swelling; Rheumatoid	Celexa [Citalopram Hydrobromide]	C	Unknown	Not Reported
Arthritis; Swelling; Thyroid	Ketoprofen	C	Unknown	Not Reported
Disorder	Losec [Omeprazole]	C		Not Reported
	Naprosyn [Naproxen]	C		Not Reported
	Rosuvastatin Calcium	C		Not Reported
	Xeljanz	C	Oral	Not Reported
	Crestor	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17763565	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231867		76 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Erythema; Off	Aziticromicina Teva Italia (Azithromycin)			S	Oral	500 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Label Use; Rash Pustular	Darunavir	S	Oral	800 Mg	Teva
	Ritonavir Sandoz	S	Oral	100 Mg	Not Reported
	Norvasc 5 Mg Compresse	S	Oral	10 Mg	Not Reported
	Clexane T	S	Subcutaneous	6000 Ku	Not Reported
	Plaquenil	S	Oral	400 Mg	Not Reported
	Eutirox	C			Not Reported
	Folifill	C			Not Reported
	Ceftriaxone Mylan Generics 2000 Mg Polvere Per Soluzione Per Infusione	C	Oral	1 Df	Not Reported
	Lasix Fiale	C			Not Reported
	Urbason Solubile	C	Intravenous (not otherwise specified)	1 Df	Not Reported
	Omeprazole	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17794557	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2020-024373		66 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Ventricular Fibrillation	Carvedilol			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported
	Irbesartan Eg			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Azithromycin Pfizer			S	Oral	250 Milligram, Once A Day		Not Reported
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17806674	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200517468			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Remicade	S	Intravenous (not otherwise specified)	Janssen
Remicade	S	Intravenous (not otherwise specified)	Janssen
Remicade	S	Intravenous (not otherwise specified)	Janssen
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Arava	S	Oral	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine /00072603/	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Intramuscular	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil /00072602/	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17806676	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517470			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Rheumatoid Arthritis; Vomiting	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17806683	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517467			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product	Remicade			S	Intravenous (not			Janssen

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Administered; Drug			otherwise specified)	
Ineffective; Hepatic	Actemra	S	Unknown	Not Reported
Enzyme Increased; Off	Enbrel	S	Subcutaneous	Not Reported
Label Use; Pneumonia;	Humira	S	Subcutaneous	Not Reported
Rheumatoid Arthritis	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Arava	C		Not Reported
	Prednisone	C		Not Reported
	Simponi	C	Subcutaneous	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17806724	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20200517462		73 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Remicade			S	Intravenous (not otherwise specified)			Janssen	
Alopecia; Anxiety;	Enbrel			S	Subcutaneous			Not Reported	
Arthralgia; Asthenia;	Humira			S	Subcutaneous	Cyclical		Not Reported	
Contraindicated Product	Methotrexate			S	Unknown			Not Reported	
Administered; Depression;	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Diarrhoea; Drug	Plaquenil /00072602/			S	Unknown			Not Reported	
Dependence; Drug	Prednisone			S	Unknown			Not Reported	
Ineffective; Drug Use									
Disorder; Fall; Fatigue;									
Headache; Inflammation;									
Joint Injury; Malaise; Pain;									
Red Blood Cell									
Sedimentation Rate									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Rheumatoid Arthritis; Synovitis	Rituxan	S	Intravenous (not otherwise specified)	Cyclical	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Unknown		Not Reported
	Desoximetasona	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17812669	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517507		57 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Cyst; Bone Erosion; Drug Ineffective; Hypertension; Therapeutic Response Decreased	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Unknown	Not Reported
	Plaquenil /00072602/	S	Unknown	Not Reported
	Desoximetasone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17812671	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200517502		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Cataract; Drug Ineffective	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Oral			Not Reported
	Celebrex			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17813033	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514296			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Orencia	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17815304	EXPEDITED (15-DAY)		DE, HO	GR-BIOVITRUM-2020GR2165		51 YR	Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Shock	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17815320	EXPEDITED (15-DAY)		DE, HO, OT	GR-BIOVITRUM-2020GR2200		74 YR	Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatomegaly; Hypoxia; Inflammatory Marker Increased; Off Label Use; Pyrexia; Shock; Splenomegaly	Anakinra			S	Intravenous (not otherwise specified)			Not Reported
	Anakinra			S				Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S				Not Reported
	Hydroxychloroquine			S				Not Reported
	Teicoplanin			S				Not Reported
	Hydrocortisone			C	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17815343	EXPEDITED (15-DAY)		DE, OT	GR-BIOVITRUM-2020GR2202		84 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anuria; Off Label Use; Shock; Splenomegaly	Anakinra			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S				Not Reported	
	Meropenem			S				Not Reported	
	Azithromycin			S				Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Teicoplanin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17816644	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514298			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Remicade			S	Intravenous (not otherwise specified)			Janssen	
	Actemra			S				Not Reported	
	Enbrel			S				Not Reported	
	Gold			S				Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Methotrexate			S				Not Reported	
	Orencia			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17824697	EXPEDITED (15-DAY)		HO	CA-ROCHE-2600447		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abscess;	Rituxan			S	Intravenous (not			Not Reported	

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Adrenal Insufficiency;			otherwise specified)	
Alanine Aminotransferase	Ceftazidime	S	Unknown	Not Reported
Increased; Ascites;	Furosemide	S	Unknown	Not Reported
Asthenia; Blood Alkaline	Mycophenolate Mofetil	S	Unknown	Not Reported
Phosphatase Increased;	Mycophenolate Mofetil	S	Unknown	Not Reported
Blood Bilirubin Increased;	Piperacillin/Tazobactam	S	Unknown	Not Reported
Blood Potassium	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Decreased; Blood	Prednisone	S	Unknown	Not Reported
Pressure Diastolic	Prednisone	S	Unknown	Not Reported
Abnormal; Blood Pressure	Prednisone	S	Unknown	Not Reported
Increased; Congestive	Rosuvastatin Calcium	S	Unknown	Not Reported
Hepatopathy; Depression;	Vancomycin Hydrochloride	S	Unknown	Not Reported
Diverticulitis; Endometrial	Rosuvastatin	S	Unknown	Not Reported
Disorder; Enterococcus	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Test Positive; Fibrosis;	Acetaminophen	C	Oral	Not Reported
Gamma-	Actonel	C	Unknown	Not Reported
Glutamiltransferase	Apo Amlo	C		Not Reported
Increased; Gastrointestinal	Apo-K	C		Not Reported
Disorder; Generalised	Diphenhydramine Hydrochloride	C	Oral	Not Reported
Oedema; Heart Rate	Epoetin Alfa	C		Not Reported
Increased; Herpes Zoster;	Escitalopram	C	Unknown	Not Reported
Hypersensitivity;	Hydrochlorothiazide	C	Unknown	Not Reported
Hypoglycaemia;	Hydroxychloroquine	C		Not Reported
Hypotension; Increased	Januvia	C	Unknown	Not Reported
Appetite; Influenza;	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
Infusion Related Reaction;	Metoprolol	C		Not Reported
Injection Site	Pantoloc [Pantoprazole]	C	Unknown	Not Reported
Extravasation; Intensive	Risedronate	C	Unknown	Not Reported
Care Unit Acquired	Slow-K	C		Not Reported
Weakness; Intervertebral	Tylenol	C		Not Reported
Disc Protrusion; Joint				
Effusion; Joint Swelling;				
Micturition Disorder;				
Myelopathy; Myopathy;				
Nasopharyngitis; Nausea;				
Nerve Compression;				
Neuropathy Peripheral;				
Neutropenia;				
Osteoarthritis;				
Pancytopenia; Peripheral				
Sensorimotor Neuropathy;				
Peritonitis; Pneumonia;				

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Pseudomonal Bacteraemia; Rheumatoid Arthritis; Septic Shock; Therapeutic Response Decreased; Vomiting; Weight Decreased; Weight Increased	Ventolin [Salbutamol Sulfate] Humalog	C C	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17825815	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204791		72 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Pyrexia	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Clexane			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Euthyrox			C	Oral	37.5 Mg, 1x/Day		Not Reported
	Lorazepam			C	Oral	2 Mg, 1x/Day		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Oral	20 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Novalgina			C	Intravenous (not otherwise specified)	1 G, Every 6 Hours As Needed		Not Reported
	Meclin			C	Oral	50 Mg, 2x/Day		Not Reported
Puran T4			C		37.5 Ug, 1x/Day		Not Reported	
Domperidone			C		10 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17825820	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204785		62 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Electrocardiogram Qt	Zitromax			S	Intravenous (not	500 Mg, 1x/Day		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication; Pyrexia	Reuquinol	S	otherwise specified)		
	Reuquinol	S	Oral	400 Mg, 2x/Day 12/12h	Not Reported
	Reuquinol	S		400 Mg, 1x/Day	Not Reported
	Reuquinol	S		200 Mg, 1x/Day	Not Reported
	Atorvastatin Calcium	C		10 Mg, 1x/Day	Not Reported
	Oseltamivir	C	Oral	75 Mg, 2x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	400 Mg, 2x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported
	Meropenem	C	Intravenous (not otherwise specified)	1 G, 3x/Day 8 / 8h	Not Reported
	Linezolid	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported
	Sodium Bicarbonate	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Bromoprida	C	Intravenous (not otherwise specified)	10 Mg, 3x/Day	Not Reported
	Potassium Chloride	C		Unk	Not Reported
	Sodium Chloride	C		Unk	Not Reported
	Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed (As Physician Criteria)	Not Reported
	Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Ug, As Needed (As Physician Criteria)	Not Reported
	Hemofol	C	Subcutaneous	5000 lu, 3x/Day	Not Reported
	Hepamax S	C		Unk	Not Reported
	Nexium [Esomeprazole Magnesium]	C		20 Mg, 1x/Day	Not Reported
	Aradois	C		50 Mg, 1x/Day	Not Reported
	Somalgin	C		81 Mg, 1x/Day	Not Reported

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Exodus [Escitalopram Oxalate]			C		10 Mg, 1x/Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17830178	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1239952		40 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Hypertransaminaemia	Hidroxicloroquina (2143a)			S	Oral	400 Mg W / 12 Hours Followed By 200 Mg W / 12 Hours. 1 Dosage Forms		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported	
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S	Oral	400 Mg C / 12 Drops.2 Dosage Forms		Not Reported	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17830292	EXPEDITED (15-DAY)		OT	NVSC2020FR145080		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiotoxicity; Dysphagia; Muscle Disorder; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 7.4 Mg/Kg/Day)		Novartis	
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17836250	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-026603		64 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypofibrinogenaemia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	

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Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Two Times A Day	Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 Gram, Once A Day	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	400 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17836482	EXPEDITED (15-DAY)	OT		CA-ROCHE-2602499		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Ciclosporin			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Neoral			S	Oral			Not Reported
	Neoral			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17836584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604914		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankle Fracture; Decreased Appetite; Drug Ineffective; Headache; Hypercholesterolaemia; Infection; Joint Swelling; Malaise; Nausea; Off Label Use; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete; Vomiting	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17836705	EXPEDITED (15-DAY)		HO	CA-ROCHE-2602962		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Arthropathy; Drug Ineffective; Fall; Fatigue; Femur Fracture; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Apo-Naproxen	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Naproxen	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17836720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605662		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Musculoskeletal Pain; Pain In Extremity; Pancreatic Carcinoma; Peripheral Swelling; Rheumatoid Arthritis; Splenectomy; Swelling; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17836926	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607346		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Angioedema; Arthropathy;	Rituximab	S	Intravenous drip	Not Reported
Asthma; Back Pain;	Actemra	S	Unknown	Not Reported
Condition Aggravated;	Apo-Azathioprine	S	Unknown	Not Reported
Drug Ineffective; Drug	Apo-Leflunomide	S	Unknown	Not Reported
Intolerance; Dyspepsia;	Azathioprine	S	Unknown	Not Reported
Food Intolerance; Hepatic	Enbrel	S	Unknown	Not Reported
Enzyme Increased;	Humira	S	Subcutaneous	Not Reported
Hypertension;	Hydroxychloroquine	S	Unknown	Not Reported
Inflammation; Injection	Hydroxychloroquine	S	Unknown	Not Reported
Site Inflammation;	Leflunomide	S	Unknown	Not Reported
Injection Site Pruritus;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Loss Of Personal	Methotrexate	S	Unknown	Not Reported
Independence In Daily	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Activities; Musculoskeletal	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Stiffness; Off Label Use;	Sulfasalazine	S	Unknown	Not Reported
Pain; Pneumonia; Pruritus;				
Pulmonary Fibrosis;				
Rheumatoid Arthritis;				
Septic Shock; Synovitis;				
Treatment Failure; Urinary				
Tract Infection; Urosepsis				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17837002	EXPEDITED (15-DAY)			US-ADVANTZ PHARMA-202004004856			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vision Blurred	Hydroxychloroquine			S		Unk		Concordia
	Xeljanz			S	Oral	5 Mg, Bid (60/Btl)		Not Reported
	Amitriptyline			S		Unk, Dose Increased Few Months Ago		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17837076	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605992			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17837078	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605414		77 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Arthralgia; Arthropathy; Back Pain; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17837158	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605967		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Carpal Tunnel Syndrome;	Actemra			S	Unknown			Not Reported	
Condition Aggravated; Drug Ineffective; Drug Intolerance; Drug Resistance; Fatigue; Gait Disturbance; Inflammation; Mouth Ulceration; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis; Rotator Cuff Syndrome; Swelling; Therapeutic Response Decreased; Tongue Ulceration; Tooth Infection; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Golimumab			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Nystatin			S	Unknown			Not Reported	
	Nystatin			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17837469	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604978		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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		Methotrexate		C	Oral				Not Reported
		Xeljanz		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17837474	EXPEDITED (15-DAY)		DS	CA-ROCHE-2608394		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Fine Motor Skill Dysfunction; Joint Swelling; Musculoskeletal Disorder; Musculoskeletal Stiffness; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Rituximab			S	Intravenous drip			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17838561	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA- GSH201801-000253			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Unilateral; Eye Burns; Visual Field Defect; Visual Impairment	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	1 Tablet Per Day (1 Df, Every Morning), Film- Coated Tablet		Concordia	
	Lanzor			C		Unk		Not Reported	
	Kardegic			C		Unk		Not Reported	
	Coaprovel			C		Unk		Not Reported	
	Ventoline			C		Unk		Not Reported	
	Rosuvastatine [Rosuvastatin]			C		Unk		Not Reported	
	Hydrochlorothiazide			C		Unk		Not Reported	

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Hydrochlorothiazide	C		Not Reported
Irbesartan	C	Unk	Not Reported
Bisoprolol	C	Unk	Not Reported
Seretide	C	Unk	Not Reported
Salbutamol	C	Unk	Not Reported
Lansoprazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17838967	EXPEDITED (15-DAY)		HO, OT	JP-ADVANS PHARMA- GSH201806-001903			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Fluid Retention; Hepatic Enzyme Increased; Herpes Zoster; Purulence; Spondylitis	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qod		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	400 Mg, Qod		Concordia
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported
	Prednisolone			S	Oral	60 Mg, Qd		Not Reported
	Prednisolone			S	Oral	45 Mg, Qd		Not Reported
	Prednisolone			S	Oral	40 Mg, Qd		Not Reported
	Prednisolone			S	Oral	35 Mg, Qd		Not Reported
	Prednisolone			S	Oral	30 Mg, Qd		Not Reported
	Prednisolone			S	Oral	25 Mg, Qd		Not Reported
	Prednisolone			S	Oral	20 Mg, Qd		Not Reported
	Prednisolone			S	Oral	17.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported
	Prednisolone			S	Oral	12.5 Mg, Qd		Not Reported
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported
	Prednisolone			S	Oral	9 Mg, Qd		Not Reported
	Prednisolone			S	Oral	8 Mg, Qd		Not Reported
	Prednisolone			S	Oral	7 Mg, Qd		Not Reported

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Prednisolone	S	Oral	6 Mg, Qd	Not Reported
Prednisolone	S	Oral	5 Mg, Qd	Not Reported
Prednisolone	S	Oral	4 Mg, Qd	Not Reported
Prednisolone	S	Oral	3 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Rituximab	S	Intravenous drip	700 Mg, Qd	Not Reported
Danazol	S	Oral	200 Mg, Qd	Not Reported
Danazol	S	Oral	300 Mg, Qd	Not Reported
Danazol	S	Oral	400 Mg, Qd	Not Reported
Danazol	S	Oral	300 Mg, Qd	Not Reported
Danazol	S	Oral	200 Mg, Qd	Not Reported
Danazol	S	Oral	100 Mg, Qd	Not Reported
Glycyron (DI-Methionine;Glycine;Glycyrrhizic Acid, Ammonium Salt)	S	Oral	9 Dosage Form, Qd	Not Reported
Samtarel	C		Unk	Not Reported
Samtarel	C			Not Reported
Slow K	C		Unk	Not Reported
Slow K	C			Not Reported
Nifedipine	C		Unk	Not Reported
Halizon	C		Unk	Not Reported
Furosemide	C		Unk	Not Reported
Magmitt	C		Unk	Not Reported
Magmitt	C			Not Reported
Januvia	C		Unk	Not Reported
Januvia	C			Not Reported
Adona [Carbazochrome Sodium Sulfonate]	C		Unk	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17838999	EXPEDITED (15-DAY)		HO	ES-ROCHE-2608114		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Dolquine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839102	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605181			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug Ineffective; Gastrointestinal Toxicity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Lipitor [Atorvastatin Calcium]			C	Oral			Not Reported	
	Xeljanz			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839109	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605281		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis;	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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Hypersensitivity; Off Label Use; Oral Disorder; Rheumatoid Arthritis; Synovitis; Transaminases Abnormal	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839141	EXPEDITED (15-DAY)		OT	CA-ROCHE-2035026		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Drug Ineffective; Drug Intolerance; Feeding Disorder; Hypersensitivity; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Stomatitis; Weight Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Varenicline Tartrate			S	Oral			Not Reported
	Acetaminophen;Oxycodone Hydrochloride			C				Not Reported
	Esomeprazole			C				Not Reported
	Magnesium;Naproxen							
	Prednisone			C				Not Reported
	Rosuvastatin Calcium			C				Not Reported
	Tofacitinib Citrate			C				Not Reported
	Valtrex			C				Not Reported

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29-May-2020	17839180	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605265		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Potassium Chloride			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839241	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2605496			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Diabetes Mellitus; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Hypersensitivity; Joint Swelling; Lip Ulceration; Mobility Decreased; Mouth Ulceration; Neutropenia; Off Label Use; Spinal Stenosis; Therapeutic Product Effect Decreased; Treatment Failure; Urinary Tract Infection; Wheelchair User	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral	20.0 Years		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

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Prednisone	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Celebrex	C	Unknown	Not Reported
Dilaudid	C	Unknown	Not Reported
Gold	C	Unknown	Not Reported
Morphine	C	Unknown	Not Reported
Penicillamine	C	Unknown	Not Reported
Tofacitinib	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839334	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605480		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Pain; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported

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Sulfasalazine			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839405	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3422032-00		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Off Label Use; Pruritus; Rash	Kaletra			S	Oral			Not Reported	
	Roactemra			S	Unknown	20 Mg/ML Concentrate		Not Reported	
	Clexane			S	Subcutaneous			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Fidato			S	Intravenous (not otherwise specified)	2g		Not Reported	
	Urbason			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839441	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608713		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypersensitivity; Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Viral Upper Respiratory Tract Infection	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	

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Methotrexate	S	Subcutaneous	Not Reported
Hydroxychloroquine	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839657	EXPEDITED (15-DAY)	DS		CA-ROCHE-2606057		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gold			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Subcutaneous			Not Reported

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Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported
Salazopyrin	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Bifidobacterium Bifidum	C		Not Reported
Celebrex	C		Not Reported
Loperamide	C		Not Reported
Pantoprazole	C		Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Simponi	C	Unknown	Not Reported
Sulfasalazine	C		Not Reported
Wellbutrin	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839754	EXPEDITED (15-DAY)	HO		CA-ROCHE-2605556			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Abnormal; Condition	Rituximab			S	Unknown			Not Reported
Aggravated; Drug	Arava			S	Unknown			Not Reported
Hypersensitivity; Drug	Benzalkonium Chloride			S	Unknown			Not Reported
Ineffective; Drug	Boric Acid			S	Unknown			Not Reported
Intolerance;	Cimzia			S	Subcutaneous			Not Reported
Gastrointestinal Toxicity;	Disodium Edetate			S	Unknown			Not Reported
Hepatotoxicity; Infection;	Enbrel			S	Subcutaneous			Not Reported
Joint Injury; Joint Stiffness;	Gold			S	Unknown			Not Reported
Joint Swelling;	Humira			S	Subcutaneous			Not Reported
Musculoskeletal Pain;								
Musculoskeletal Stiffness;								
Neoplasm Malignant; Pain								
In Extremity; Pulmonary								
Toxicity; Therapeutic								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Effect Incomplete; Therapy Non-Responder; Treatment Failure	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phenylephrine Hydrochloride	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Sodium Borate	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Subcutaneous	Not Reported
	Celebrex	C		Not Reported
	Ibuprofen	C		Not Reported
	Lipitor [Atorvastatin Calcium]	C		Not Reported
	Prednisone	C		Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839787	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02477			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Premature Delivery	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Tacrolimus			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17839858	EXPEDITED (15-DAY)		DS	CA-ROCHE-2605576		37 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Aleve			C				Not Reported
	Arava			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840168	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605008		30 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Drug Hypersensitivity; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Synovitis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840184	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605215		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Infection; Joint Stiffness; Osteomyelitis; Pain	Actemra			S	Subcutaneous			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840270	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605515		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Condition Aggravated; Drug Ineffective; Frustration Tolerance Decreased; Impaired Work Ability; Injection Site Bruising; Injection Site Erythema; Injection Site Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Musculoskeletal Stiffness; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation; Swelling	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Ibuprofen			C	Unknown			Not Reported

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Lisinopril	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840309	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1241349		84 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200mg Bid, 400 Mg		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840349	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606318		47 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; Blood Glucose Increased; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Blood Pressure Diastolic Increased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Bronchitis;	Cimzia			S	Unknown			Not Reported
Cardiac Disorder; Contusion; Croup	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Infectious; Drug Ineffective; Fatigue;	Methotrexate			S	Unknown			Not Reported
Fibromyalgia; Foot Deformity; Gastroenteritis	Rosuvastatin Calcium			S	Unknown			Not Reported
Viral; Headache; Heart Rate Increased;	Sulfasalazine			S	Unknown			Not Reported
Hypersensitivity; Hypertension;	Folic Acid			C				Not Reported
Hypotension;	Humalog			C	Unknown			Not Reported
Immunosuppression;	Sertraline Hydrochloride			C				Not Reported
	Synthroid			C				Not Reported

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Influenza; Infusion Related
Reaction; Insomnia;
Musculoskeletal Stiffness;
Nasopharyngitis; Nausea;
Oropharyngeal Pain; Pain;
Pain In Extremity;
Pertussis; Productive
Cough; Rash; Stress;
Therapeutic Response
Decreased; Treatment
Failure; Weight
Decreased; Weight
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840377	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2020M1051907		11 YR	Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Off Label Use; Shock	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Mylan	
	Methylprednisolone			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840422	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608715		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Drug Ineffective; Gamma-Glutamyltransferase Increased; Hepatic Steatosis; Upper Respiratory Tract Infection	Rituximab			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Actemra			C	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840536	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605589		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Back Pain; Drug Ineffective; Infection; Influenza; Pneumonia; Tooth Fracture; Vaccination Site Cellulitis; Vaccination Site Induration	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Cortisone			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Pneumococcal Vaccine			S	Unknown	For 1 Month		Not Reported	
	Andriol			C	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Eprosartan Mesilate;Hydrochlorothiazide			C				Not Reported	
	Estrogel			C	Unknown			Not Reported	
	Nifedipine			C				Not Reported	
	Prometrium [Progesterone]			C				Not Reported	
	Rosuvastatin Calcium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840626	EXPEDITED (15-DAY)		CA, OT	FR-PFIZER INC-2020208534			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Achromotrichia Congenital; Maternal Exposure During Pregnancy	Zithromax			S	Transplacental	250 Mg, 1x/Day		Pfizer	
	Hydrocortisone Roussel [Hydrocortisone Acetate]			S	Transplacental	100 Mg, 1x/Day		Not Reported	
	Parlodel			S	Transplacental	20 Mg, 1x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Transplacental	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840766	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1051938		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction;	Azithromycin	S	Unknown	Unk	Not Reported
Electrocardiogram Qt	Hydroxychloroquine Sulfate	S	Unknown	Unk	Mylan
Prolonged; Intentional					
Product Misuse; Off Label					
Use					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840956	EXPEDITED (15-DAY)		DE, OT	BE-ADVANSZ PHARMA-202005005958			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17840986	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605191		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Cardiovascular Disorder; Condition	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Aggravated; Cystitis; Deformity; Depressed	Arava			S	Unknown			Not Reported
Mood; Dermatitis; Drug	Celebrex			S	Unknown			Not Reported
Ineffective; Encephalitis; Encephalitis Brain Stem;	Enbrel			S	Subcutaneous			Not Reported
Fall; Fibromyalgia;	Hydroxychloroquine			S	Unknown			Not Reported
Immobile; Immune System Disorder;	Methotrexate			S	Unknown			Not Reported
Immunodeficiency; Joint	Prednisone			S	Unknown			Not Reported
Destruction; Loss Of	Dilaudid			C	Unknown			Not Reported
Personal Independence In	Furosemide			C	Unknown			Not Reported
Daily Activities; Memory	Hydromorph Contin			C	Unknown			Not Reported
Impairment; Pain;	Lyrca			C	Oral			Not Reported
Peripheral Swelling;								
Psychiatric Symptom;								
Rheumatoid Arthritis; Rib								
Fracture; Scar; Seizure;								
Sepsis; Spinal Deformity;								
Vomiting								

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841249	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605225		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Androgenetic Alopecia; Aphthous Ulcer; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Increased; Diffuse Alopecia; Drug Ineffective; Heart Rate Decreased; Infection; Infusion Related Reaction; Nasopharyngitis; Rash; Stomatitis; White Blood Cell Count Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Asa			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported
	Candesartan			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Rosuvastatin Calcium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841275	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1240532		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	160 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841284	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1240452		60 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Gastrointestinal Pain	Hidroxyclorequina (2143a)			S	Oral	200 Mg		Teva
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	1 Dosage Form		Not Reported
	Omeprazol (2141a)			C	Oral	20 Mg		Not Reported
	Paracetamol 1.000 Mg 40 Comprimidos			C	Oral	1 Gm		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841446	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605474		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Joint Swelling; Off Label Use; Pneumonia; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported
	Lidocaine Hydrochloride			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Cefalexin			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841450	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1241324		59 YR	Male	PRT

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatic Function Abnormal	Hydroxychloroquine			S	Oral	200 Mg Bid. Unit Dose: 400 Mg		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841644	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020205717		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Bilirubin Increased; Coronavirus Infection; Drug Ineffective; Hepatic Function Abnormal; Hypoxia; Inflammation; Localised Oedema; Pneumonia; Pseudomonas Infection; Severe Acute Respiratory Syndrome; Spinal Disorder; Stenotrophomonas Infection	Lederfoline			S		Unk		Pfizer
	Tazocilline			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Lovenox [Enoxaparin Sodium]			S	Subcutaneous	2 Df, 1x/Day (2x/Day (8000 Ui)		Not Reported
	Perfalgan			S		1 G, 4x/Day		Not Reported
	Bactrim			S		Unk		Not Reported
	Inexium [Esomeprazole Magnesium]			S	Intravenous (not otherwise specified)	40 Mg, 1x/Day		Not Reported
	Rocephine			S		Unk		Not Reported
	Mucomyst [Acetylcysteine]			S		4 Df, 1x/Day, (1 Df 4x/Day (Sachet Sng))		Not Reported
	Dextromethorphan Hydrobromide			S		Unk		Not Reported
	Catapressan [Clonidine Hydrochloride]			S		Unk		Not Reported
	Claventin [Clavulanate Potassium;Ticarcillin Disodium]			S		Unk		Not Reported
	Tavanic			S		500 Mg, 2x/Day		Not Reported
	Eupressyl [Urapidil]			S		Unk		Not Reported
	Fortum [Ceftazidime]			S		2 G, 3x/Day		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported
	Tranxene			S		2.5 Mg, Per Hour		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841669	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2020M1051990		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Off Label Use	Enoxaparin			S	Subcutaneous	60 Milligram, Qd, 60 Mg		Not Reported	
	Azithromycin			S	Oral	500 Mg Dia		Not Reported	
	Hidroxicloroquina /00072601/			S	Oral	400 Mg Dia		Mylan	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608333			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Abnormal; C-Reactive Protein Increased; Cataract; Drug Ineffective; Laboratory Test Abnormal; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal	Rituximab			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 397 Days		Not Reported	
	Arava			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Unknown	Therapy Duration: 6 Years		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown	Therapy Duration: 560		Not Reported	
	Orencia			S	Unknown	Therapy Duration: 471 Days		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Therapy Duration: 10 Years		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Therapy Duration: 471		Not Reported	

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				otherwise specified)	Days				
	Sulfasalazine		S	Oral					Not Reported
	Xeljanz		S	Oral					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841767	EXPEDITED (15-DAY)		HO	NVSC2020US147932		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Intentional Overdose; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	10-11 G		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841807	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605509		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Blood Creatinine Increased; Diarrhoea; Drug Ineffective; Limb Discomfort; Musculoskeletal Discomfort; Off Label Use; Pain; Pharyngeal Oedema; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Arava			C				Not Reported
	Hydroxychloroquine			C				Not Reported
	Methotrexate			C				Not Reported
	Xeljanz			C	Oral			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842163	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-042185			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Subcutaneous	Unk		Not Reported	
	Enbrel			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituximab			S	Intravenous drip	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842419	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605453		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Joint Swelling; Neutropenia; Off Label Use; Red Blood Cell Sedimentation Rate Increased; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased; Urinary Tract Infection	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	

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Desoximetasone	C	Unknown	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842449	EXPEDITED (15-DAY)		DE, HO	SK-ROCHE-2388944		57 YR	Male	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cerebral	Mycophenolate Mofetil			S	Unknown			Not Reported
Infarction; Dizziness;	Hydroxychloroquine			S	Unknown			Not Reported
Hypotension; Intentional	Methotrexate			S	Unknown			Not Reported
Product Use Issue; Mental	Cyclophosphamide			S	Unknown			Not Reported
Impairment; Off Label	Azathioprine			S	Unknown			Not Reported
Use; Pneumonia;	Cyclosporine			S	Unknown			Not Reported
Progressive Multifocal	Belimumab			S	Unknown			Not Reported
Leukoencephalopathy;	Prednisone			S	Unknown			Not Reported
Respiratory Failure;								
Speech Disorder; Tremor								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842621	EXPEDITED (15-DAY)		LT	CA-ROCHE-2608325		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product	Rituximab			S	Unknown			Not Reported
Administered; Disease	Golimumab			S	Unknown			Not Reported
Progression; Dysphonia;	Hydroxychloroquine			S	Unknown			Not Reported
Dyspnoea; Odynophagia;	Methotrexate			S	Unknown			Not Reported
Product Use In	Orencia			S	Unknown			Not Reported
Unapproved Indication;	Sulfasalazine			S	Unknown			Not Reported
Rheumatoid Arthritis;								
Stridor								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842629	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609222			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842639	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604987			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hand Deformity; Joint Stiffness; Nausea; Pain; Therapeutic Product Effect Decreased; Thyroid Disorder	Actemra			S	Unknown			Not Reported	
	Apo-Hydroxyquine			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842640	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605519		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer; Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Parenteral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17842706	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605538		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown	5.0 Months		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous	8.0 Months		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17845062	DIRECT	Y	DE			30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Hydroxychloroquine			S	Oral			Actavis	
	Actemra			S	Intravenous (not otherwise specified)	Other Frequency:X1;		Genentech	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	12861315	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1843584		75 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Blood Creatinine Increased; Blood Magnesium Increased; Blood Potassium Increased; Bone Cyst; Bone Hypertrophy; Contraindicated Product Administered; Crohn'S Disease; Crohn'S Disease; Cyst; Deafness Neurosensory; Deformity; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Dry Eye; Epigastric Discomfort; Exostosis; Fatigue; Gastrointestinal Disorder; Hypersensitivity; Infection; Intentional Product Use Issue; Joint Swelling; Mobility Decreased; Musculoskeletal Stiffness; Myocardial Infarction;	Actemra			S	Intravenous (not otherwise specified)	Therapy Duration: 2 Years		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous	Therapy Duration: 7 Years		Not Reported	
	Fentanyl			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Subcutaneous			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)	Therapy Duration: 330 Days		Not Reported	
	Orencia			S	Vaginal			Not Reported	
	Oxycontin			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral	Therapy Duration: 5 Years		Not Reported	
	Gabapentin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nausea; Off Label Use;	Nortriptyline Hydrochloride	S	Oral	Not Reported
Osteoarthritis; Osteopenia;	Nortriptyline Hydrochloride	S	Oral	Not Reported
Osteosclerosis; Pain; Pain	Hydroxychloroquine	S	Unknown	Not Reported
In Extremity; Pleural	Myochrysine	S	Intramuscular	Not Reported
Fibrosis; Pleural	Arava	S	Oral	Not Reported
Thickening; Presbycusis;	Apo-Gabapentin	S	Oral	Not Reported
Renal Impairment;	Actonel	C	Unknown	Not Reported
Rheumatoid Arthritis; Skin	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Lesion; Sleep Disorder;	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Therapeutic Product Effect	Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Decreased; Treatment	Ferrous Gluconate	C	Unknown	Not Reported
Failure	Other Ophthalmologicals	C	Ophthalmic	Not Reported
	Lomotil [Atropine	C	Unknown	Not Reported
	Sulfate;Diphenoxylate			
	Hydrochloride]			
	Nasonex	C	Unknown	Not Reported
	Esomeprazole	C	Unknown	Not Reported
	Omega-3 Fatty Acids	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Trazodone Hydrochloride	C	Oral	Not Reported
	Tylenol	C	Oral	Not Reported
	D-Alpha Tocopherol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Esomeprazole Magnesium	C	Unknown	Not Reported
	Trihydrate			
	Esomeprazole Magnesium	C	Unknown	Not Reported
	Trihydrate			
	Fergon	C	Unknown	Not Reported
	Loperamide Hydrochloride	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Perphenazine	C	Oral	Not Reported
Trazodone	C		Not Reported
Aclasta	C	Intravenous (not otherwise specified) Herbal Tea	Not Reported
Aclasta	C	Unknown Herbal Tea	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Nicotinamide	C	Unknown	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Sodium Ascorbate	C	Unknown	Not Reported
Thiamine Hydrochloride	C		Not Reported
Vitamin A [Retinol]	C		Not Reported
Vitamin D3	C	Unknown	Not Reported
Zoledronic Acid	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	15317460	EXPEDITED (15-DAY)		OT	CA-ROCHE-2172797		16 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthropathy; Crohn'S Disease; Drug Hypersensitivity; Drug Intolerance; Gait Disturbance; Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Oral	Not Reported
Apo-Leflunomide	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Oral	Not Reported
Folic Acid	C	Oral	Not Reported
Leflunomide	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Xeljanz	C	Oral	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17023732	EXPEDITED (15-DAY)		OT	CA-ROCHE-2459446		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Injection Site Bruising; Injection Site Erythema; Injection Site	Actemra			S	Unknown	Dosage Form : Not Specified		Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Dosage Form : Not Specified		Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pruritus; Injection Site Rash; Injection Site Reaction; Injection Site Swelling; Joint Swelling; Nasopharyngitis; Off Label Use; Rheumatoid Arthritis; Suicidal Ideation	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Prednisone	S	Unknown	Dosage Form : Not Specified	Not Reported
	Alendronate Sodium	C	Unknown		Not Reported
	Fosamax	C	Unknown		Not Reported
	Ibuprofen	C	Unknown	Dosage Form : Not Specified	Not Reported
	Lisinopril	C	Unknown		Not Reported
	Vitamin D3	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17260308	EXPEDITED (15-DAY)		OT	CA-ROCHE-2517545		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Impaired Work Ability; Interstitial Lung Disease; Off Label Use; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Asa			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Lantus			C	Subcutaneous			Not Reported
	Lozide [Indapamide]			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metformin	C	Unknown	Not Reported
Naprosyn [Naproxen]	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Ramipril	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17295895	EXPEDITED (15-DAY)	OT		CA-ROCHE-2524847		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Actemra			S	Unknown			Not Reported
Arthropathy; Condition	Rituxan			S	Intravenous (not	Solution For Infusion		Not Reported
Aggravated;					otherwise specified)			
Contraindicated Product	Rituxan			S	Intravenous (not			Not Reported
Administered; Drug					otherwise specified)			
Hypersensitivity; Drug	Arava			S	Oral			Not Reported
Ineffective; Finger	Arava			S	Unknown			Not Reported
Deformity; Limb	Benzylpenicillin			S	Unknown			Not Reported
Operation; Pain;	Codeine			S	Unknown			Not Reported
Peripheral Swelling; Rash;	Enbrel			S	Subcutaneous			Not Reported
Swelling; Tendon	Gold			S	Unknown			Not Reported
Operation; Tenosynovitis;	Humira			S	Subcutaneous			Not Reported
Treatment Failure;	Hydroxychloroquine			S	Unknown			Not Reported
Urticaria; Wrist Surgery	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not			Not Reported
					otherwise specified)			
	Plaquenil [Hydroxychloroquine			S	Oral			Not Reported
	Sulfate]							
	Remicade			S	Intravenous (not	Powder For Solution For		Not Reported
					otherwise specified)	Infusion		
	Rocuronium Bromide			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Parenteral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
Methotrexate	S	Unknown	Solution	Not Reported
Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17351049	EXPEDITED (15-DAY)		OT	CA-ROCHE-2531131		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Cytology Abnormal; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Therapeutic Product Effect Decreased; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Lyrica			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17406344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2541854			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Folic Acid			C	Oral			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17454837	EXPEDITED (15-DAY)		OT	CA-ROCHE-2552651		75 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Cardiovascular Disorder; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inflammation; Joint Swelling; Muscle Spasms; Red Blood Cell Sedimentation Rate Increased; Urticaria	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Infliximab	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Parenteral		Not Reported
	Orencia	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Simponi	S	Unknown		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Gold	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Leflunomide	S	Oral		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Remicade	S	Unknown		Not Reported
	Rituximab	S	Subcutaneous		Not Reported
	Rituximab	S	Unknown		Not Reported
	Sodium Aurothiomalate	S	Unknown		Not Reported
	Azathioprine	C			Not Reported
	Ciclosporin	C	Unknown		Not Reported
	Minocycline	C			Not Reported
	Penicillamine	C			Not Reported
	Prednisone	C			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actemra	C	Unknown	Not Reported
Cyclosporine	C		Not Reported
D-Penicillamine	C		Not Reported
Phenylbutazone	C		Not Reported
Prednisolone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17559399	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2018- 03346		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Etanercept			S	Subcutaneous			Not Reported
	Etanercept			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	Unknown		Not Reported
	Anakinra			S	Unknown	Unknown		Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Unknown	Unknown		Not Reported
	Apo-Leflunomide			S	Oral	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Unknown	Unknown		Not Reported
	Azathioprine			S	Oral	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unknown, Powder For Solution		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unknown, Solution		Not Reported
	Gold			S	Intramuscular	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Unknown	Not Reported
Imuran	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown	Unknown	Not Reported
Leflunomide	S	Unknown		Not Reported
Leflunomide	S	Oral	Unknown	Not Reported
Plaquenil	S	Unknown	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Unknown	Not Reported
Actemra	S	Unknown	Unknown	Not Reported
Humira	S	Subcutaneous		Not Reported
Orencia	S	Unknown	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unknown	Not Reported
Rituximab	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unknown	Not Reported
Sulfasalazine	C	Unknown	Unknown	Not Reported
Wellbutrin	C	Unknown	Unknown	Not Reported
Xeljanz	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17675643	EXPEDITED (15-DAY)		DE, OT	ES-HETERO-HET2020ES00415		75 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Levofloxacin			S	Unknown	Unk		Hetero
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enoxaparin Sodium		C	Unknown	Unk, Qd	Not Reported				
Prednisona		C	Unknown	Unk, Qd	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17710430	EXPEDITED (15-DAY)	DE		IT-TEVA-2020-IT-1226892		70 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Transaminases Increased	Azitromicina Teva 500 Mg Comprese Rivestite Con Film Plaquenil			S	Oral	500 Mg		Not Reported	
				S	Oral	400 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17763532	EXPEDITED (15-DAY)	HO		IT-TEVA-2020-IT-1231868		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme; Off Label Use; Oral Disorder; Rash Pruritic; Rash Pustular; Rash Vesicular; Stevens-Johnson Syndrome	Hydroxychloroquine			S	Oral	400 Mg		Teva	
	Symtuza			S	Oral	1 Dosage Forms		Not Reported	
	Triumeq			S	Oral	1 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17765857	EXPEDITED (15-DAY)	OT		CA-ROCHE-1710942		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Contraindicated Product Administered; Drug Dependence; Drug Ineffective; Drug Specific Antibody Present; Drug Use Disorder; Gait Inability; Muscular Weakness; Nausea; Rheumatoid Arthritis;	Actemra			S	Unknown			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

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Therapeutic Product Effect Decreased; Treatment Failure	Humira	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Subcutaneous	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Cortisone	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17777966	EXPEDITED (15-DAY)	HO, OT		LV-ROCHE-2599087		12 YR	Female	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Pneumonitis; Systemic Lupus Erythematosus; Weight Decreased	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S				Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown	For Short Time Period (1-2 Weeks). Stopped Due To		Not Reported

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Rituximab	C	Unknown	Skin Eruptions	Not Reported
Cyclophosphamide	C	Unknown	For Short Time Period (1-2 Weeks)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17795926	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235484		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematousus	Prednisone			S	Unknown			Actavis
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia Single-Use Prefilled Syringe			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Reactine [Cetirizine]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral	2 Gram Daily;		Not Reported
	Xeljanz			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17842784	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609160			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Arthralgia; Drug Ineffective; Joint Swelling	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Azathioprine			S	Unknown	Not Specified		Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Amitriptyline			C				Not Reported
	Cefazolin			C				Not Reported
	Clindamycin			C				Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol W/Codeine No. 3			C				Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17842787	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609352		71 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Dizziness; Nausea; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17842862	EXPEDITED (15-DAY)		OT	NVSC2020IT148686		43 YR	Female	ITA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	400 Mg, Qd		Novartis	
	Mycophenolate Mofetil			S	Unknown	1 Df, Qd (Unk Unk, Qd)		Not Reported	
	Prednisone			S	Unknown	15 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	50 Mg, Qd, Tapering Dose		Not Reported	
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	25 Mg Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	15 Mg, Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	12.5 Mg, Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	15 Mg, Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	12.5 Mg, Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	10 Mg, Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	7.5 Mg, Qd, Dose Tapering		Not Reported	
	Prednisone			S	Unknown	10 Mg, Qd, Dose Tapering		Not Reported	
	Envarsus			S	Unknown	1 Df, Qd (Unk, Qd)		Not Reported	
	Belimumab			S	Unknown	Unk		Not Reported	
	Belimumab			S	Unknown	Unk		Not Reported	
	Belimumab			S	Unknown	Unk		Not Reported	
	Belimumab			S	Unknown	Unk		Not Reported	
	Immunoglobulin I.V			C	Unknown	Unk		Not Reported	
	Rituximab			C	Unknown	Unk		Not Reported	
	Methylprednisolone			C	Unknown	Unk (Pulses)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17842917	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606101			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Chest Pain; Eye Ulcer; Foot Deformity; Hand Deformity; Headache; Injection Site Reaction	Actemra			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Kevzara			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			C	Unknown			Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17842947	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606357			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Off Label Use; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported

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Sulfasalazine	S	Oral	Not Reported
Tylenol	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17842985	EXPEDITED (15-DAY)	OT		CA-ROCHE-2606840			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606641			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Infusion Related Reaction; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematousus; Treatment Failure; Wound	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Methotrexate			S	Intra-arterial			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Phthalylsulfathiazole			S	Unknown				Not Reported

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	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Subcutaneous	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Certolizumab Pegol	S	Subcutaneous	Not Reported
	Fosamax	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606173		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Drug Ineffective; Intestinal Perforation	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843015	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-026288		70 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Azithromycin			S	Unknown	Unk		Aurobindo	
Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843201	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606270		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Actemra			S	Unknown			Not Reported	
Abdominal Pain Upper;	Arava			S	Unknown			Not Reported	
Alopecia; Arthralgia; Bone Pain; Burning Sensation;	Calcium Folate			S	Oral			Not Reported	
Choking; Condition	Enbrel			S	Unknown			Not Reported	
Aggravated; Cough; Drug	Folic Acid			S	Oral			Not Reported	
Hypersensitivity; Drug	Humira			S	Subcutaneous			Not Reported	
Ineffective; Drug	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Intolerance; Ear Pain;	Leflunomide			S	Oral			Not Reported	
Facial Pain; Facial	Methotrexate			S	Unknown			Not Reported	
Paralysis; Fatigue;	Methotrexate			S	Oral			Not Reported	
Fibromyalgia; Foot Deformity; Gait	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
Disturbance; Headache;	Prednisone			S	Oral			Not Reported	
Hot Flush; Hypoaesthesia;	Sulfasalazine			S	Unknown			Not Reported	
Immune System Disorder;	Xeljanz			S	Oral			Not Reported	
Influenza Like Illness;	Xeljanz			S	Oral			Not Reported	
Insomnia; Joint Range Of Motion Decreased;	Acetaminophen			C	Oral			Not Reported	
Lipoma; Melanocytic	Acetaminophen;Oxycodone			C	Oral			Not Reported	
Naevus; Musculoskeletal	Hydrochloride								
Stiffness; Nasal	Celebrex			C	Unknown			Not Reported	
Discomfort;	Desoximetasone			C	Unknown			Not Reported	
Nasopharyngitis; Nausea;	Ergocalciferol			C	Unknown			Not Reported	
Night Sweats;									
Oropharyngeal									
Discomfort; Osteoporosis;									
Pain; Pain In Extremity;									
Pain In Jaw; Pelvic									
Prolapse; Peripheral									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coldness; Platelet Count Decreased; Post Procedural Infection; Rheumatoid Arthritis; Rhinorrhoea; Skin Mass; Therapeutic Product Effect Decreased; Throat Irritation	Fentanyl	C	Unknown	Not Reported
	Gabapentin	C	Oral	Not Reported
	Metformin	C	Oral	Not Reported
	Hydrochloride;Sitagliptin	C	Unknown	Not Reported
	Oxycodone Hydrochloride	C	Unknown	Not Reported
	Perindopril Erbumine	C	Oral	Not Reported
	Rabeprazole	C	Oral	Not Reported
	Ranitidine	C	Oral	Not Reported
	Rosuvastatin Calcium	C	Oral	Not Reported
	Sitagliptin	C	Oral	Not Reported
	Synthroid	C	Oral	Not Reported
	Tylenol	C	Unknown	Not Reported
	Zopiclone	C	Oral	Not Reported
	Zostavax	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606334			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Pseudoephedrine Hcl	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606521		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Irritable Bowel Syndrome; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843214	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606426			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Nausea; Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission; Synovitis; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting; White Blood Cell Count Decreased	Actemra			S	Unknown			Not Reported
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843218	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606612		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Burning Sensation; C-Reactive Protein Abnormal; Colitis; Drug Ineffective; Drug Intolerance; Intestinal Polyp; Joint Swelling; Leukopenia; Memory	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Impairment; Mobility Decreased;	Methotrexate	S	Unknown	Not Reported
Nephrolithiasis; Off Label Use; Pain; Pain In Extremity; Peripheral Swelling; Product Dose Omission	Orencia	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843226	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606514		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diverticulitis; Therapeutic Product Effect Incomplete; Therapeutic Response Decreased	Actemra			S	Subcutaneous			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843228	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606627			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Ineffective; Joint Swelling; Off Label Use; Prescribed Underdose; Product Use Issue	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843240	EXPEDITED (15-DAY)	HO		CA-ROCHE-2609163			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss Of Personal Independence In Daily Activities; Obesity; Off Label Use; Polyarthritis; Psoriasis; Red Blood Cell Sedimentation Rate Increased; Septic Shock; Synovitis; Vomiting	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Naproxen			S	Unknown			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Gamastan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Infliximab			S	Unknown			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Triamcinolone

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606810		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Calcium/Vitamin D3			C				Not Reported
	Hydrocortisone			C	Unknown			Not Reported
	Pantoloc [Pantoprazole]			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Tylenol 8 Hr Arthritis Pain			C	Unknown			Not Reported
Xarelto			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843266	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605626		72 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Swelling; Candida Infection; Condition Aggravated; Drug Ineffective; Drug Interaction; Headache; Hepatotoxicity; Joint Swelling; Loss Of	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Personal Independence In	Arava	S	Unknown		Not Reported
Daily Activities; Nausea;	Arava	S	Oral		Not Reported
Neoplasm Malignant; Off	Arava	S	Unknown		Not Reported
Label Use; Oral	Celebrex	S	Unknown		Not Reported
Candidiasis; Pain;	Enbrel	S	Subcutaneous	Duration :7 Years	Not Reported
Peripheral Swelling;	Humira	S	Unknown	Duration :7 Years	Not Reported
Prescribed Overdose;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Swelling; Therapeutic	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Product Effect Decreased;	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Therapeutic Response	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
Decreased; Thyroid	Hydroxychloroquine	S	Unknown		Not Reported
Neoplasm; Toxicity To	Leflunomide	S	Oral		Not Reported
Various Agents; Treatment	Leflunomide	S	Oral		Not Reported
Failure	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous	Duration: 13.0 Years	Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Prednisone	S	Unknown		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Tofacitinib	S	Unknown		Not Reported
	Tofacitinib Citrate	S	Unknown		Not Reported
	Xeljanz	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843333	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604955			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Joint Swelling; Neutropenia; Off Label Use; Osteoarthritis; Product Use Issue; Red Blood Cell Sedimentation Rate Increased; Therapy Partial Responder; Urinary Tract Infection	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous Frequency: Cyclical	Not Reported
	Enbrel	C	Subcutaneous	Not Reported
	Humira	C	Subcutaneous	Not Reported
	Orencia	C	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843367	EXPEDITED (15-DAY)	HO		CA-ROCHE-2605541		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anti- Neutrophil Cytoplasmic Antibody Positive	Actemra			S	Subcutaneous			Not Reported
Vasculitis; Arthralgia; Chest Pain; Diarrhoea;	Rituximab			S	Intravenous drip			Not Reported
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Headache;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Hypersensitivity; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Nausea; Off Label Use; Pain;	Apo-Leflunomide			S	Unknown			Not Reported
Proteinuria; Rheumatoid Arthritis; Treatment Failure; Vasculitis	Arava			S	Oral			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Oral			Not Reported
	Azathioprine Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Gold			S	Intramuscular			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Infliximab			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Penicillamine	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Anakinra	S	Subcutaneous	Not Reported
Cyclophosphamide	C	Intravenous (not otherwise specified)	Not Reported
Docusate Sodium	C	Oral	Not Reported
Doxycycline	C	Oral	Not Reported
Elavil [Amitriptyline Hydrochloride]	C		Not Reported
Prednisone	C	Oral	Not Reported
Sulfasalazine	C	Oral	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Tobramycin	C	Unknown	0.3 Percent
Wellbutrin	C		Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843368	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605484		54 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Arthralgia; Arthropathy; Asthma; Drug Ineffective; Drug Intolerance; Fatigue; Fine Motor Skill Dysfunction; Gastric Disorder; Gastrointestinal Disorder; Hip Arthroplasty;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypertension;	Cimzia	S	Subcutaneous	Not Reported
Inflammation; Joint Range	Enbrel	S	Subcutaneous	Not Reported
Of Motion Decreased;	Humira	S	Subcutaneous	Not Reported
Joint Stiffness; Joint	Hydroxychloroquine	S	Unknown	Not Reported
Swelling; Loss Of	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Personal Independence In	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Daily Activities; Mobility	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Decreased; Motor	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Dysfunction;	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Musculoskeletal Pain;	Methotrexate	S	Oral	Not Reported
Musculoskeletal Stiffness;	Methotrexate	S	Unknown	Not Reported
Off Label Use; Pain;	Orencia	S	Subcutaneous	Not Reported
Pruritus; Rheumatoid	Prednisone	S	Unknown	Not Reported
Factor Positive;	Remicade	S	Intravenous (not otherwise specified)	Not Reported
Seronegative Arthritis;	Xeljanz	S	Oral	Not Reported
Swelling; Synovitis;	Sulfasalazine	C	Unknown	Not Reported
Therapeutic Product Effect				
Decreased; Urticaria				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606876			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Contraindicated	Apo-Prednisone			S	Unknown			Not Reported
Product Administered;	Arava			S	Unknown			Not Reported
Drug Ineffective;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Glossodynia; Maternal	Cimzia			S	Subcutaneous			Not Reported
Exposure During	Cortisone Acetate			S	Unknown			Not Reported
Pregnancy; Pain;	Diclofenac			S	Unknown			Not Reported
Pemphigus; Product Use	Enbrel			S	Subcutaneous			Not Reported
Issue; Rheumatoid	Folic Acid			S	Unknown			Not Reported
Arthritis; Systemic Lupus	Fosamax			S	Unknown			Not Reported
Erythematousus								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843411	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606364			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arava	C	Unknown	Not Reported
Prednisone	C		Not Reported
Simponi	C		Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843412	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608827			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843413	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609657		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaphylactic Reaction; Rash; Treatment Failure; Urticaria	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843454	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606986			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Phthalylsulfathiazole	S	otherwise specified)	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Topicort [Desoximetasone]	S	Topical	Not Reported
	Cimzia	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843455	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606569			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Arthropathy;	Alendronate Sodium			S	Unknown			Not Reported
Contraindicated Product	Arava			S	Oral			Not Reported
Administered; Discomfort;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Drug Ineffective; Fatigue;	Cimzia			S	Subcutaneous			Not Reported
Glossodynia; Hand	Cortisone Acetate			S	Unknown			Not Reported
Deformity; Infusion	Desoximetasone			S	Oral			Not Reported
Related Reaction;	Diclofenac Sodium			S	Unknown			Not Reported
Maternal Exposure During	Enbrel			S	Subcutaneous			Not Reported
Pregnancy; Off Label Use;	Folic Acid			S	Unknown			Not Reported
Pain; Pemphigus; Product	Humira			S	Subcutaneous			Not Reported
Use Issue; Rash;	Hydroxychloroquine			S	Unknown			Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine			S	Oral			Not Reported
Swelling; Systemic Lupus	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
Erythematous; Treatment	Methotrexate			S	Intra-arterial			Not Reported
Failure; Wound	Orencia			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843464	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606667		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Joint Swelling; Loss Of Personal Independence In Daily Activities; Malaise; Pain; Pain In Extremity; Peripheral Swelling; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Somnolence; Visual Impairment	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeine	C	Unknown	Not Reported
Leflunomide	C	Unknown	Not Reported
Meloxicam	C	Unknown	Not Reported
Methotrexate	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843468	EXPEDITED (15-DAY)	CA		CA-ROCHE-2608792			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Acne Cystic; Condition Aggravated; Drug Ineffective; Drug Intolerance; Insomnia; Intentional Product Use Issue; Off Label Use; Rheumatoid Arthritis	Anakinra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Oral			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Orencia			S	Endocervical			Not Reported
	Rituximab			S	Unknown			Not Reported
	Vioxx			S	Unknown			Not Reported
	Xeljanz			C				Not Reported
	Leflunomide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2020	17843469	EXPEDITED (15-DAY)	OT		CA-ROCHE-2608976		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Wellbutrin	C	Unknown	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17064085	EXPEDITED (15-DAY)		OT	CA-ROCHE-2469680		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Contraindicated Product Administered; Dizziness; Drug Ineffective; Drug Intolerance; Nausea; Off Label Use; Prescribed Underdose	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Naprosyn [Naproxen]			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rituximab

S

Intravenous (not
otherwise specified)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17552505	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-021419			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Arthropathy; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	162 Milligram		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Remicade			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Azathioprine			C	Unknown	162 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2586473		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Renal Failure; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843654	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

BMS-2020-042221

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843673	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609647			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Treatment Failure; Vomiting	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Frequency: Every 1 Days		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843674	EXPEDITED (15-DAY)		HO	CA-ROCHE-2608807		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Adverse Event;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Arthropathy; Breast Cancer Stage Iii; Condition	Arava			S	Unknown			Not Reported
Aggravated; Depression;	Cefazolin			S	Unknown			Not Reported
Diarrhoea; Drug	Certolizumab Pegol			S	Subcutaneous			Not Reported
Hypersensitivity; Drug	Certolizumab Pegol			S	Subcutaneous			Not Reported
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Gait Disturbance; Gait Inability;	Humira			S	Subcutaneous			Not Reported
Hand Deformity; Infection;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Joint Range Of Motion Decreased; Memory	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Impairment;	Leflunomide			S	Oral			Not Reported
Musculoskeletal Disorder;	Methotrexate			S	Subcutaneous			Not Reported
Nausea; Off Label Use;	Methotrexate			S	Subcutaneous			Not Reported
Ovarian Cancer; Rash;	Orencia			S	Unknown			Not Reported
Rheumatoid Arthritis;	Remicade			S	Unknown			Not Reported
Rheumatoid Nodule;	Sodium Aurothiomalate			S	Unknown			Not Reported
Sleep Disorder;	Sulfasalazine			S	Unknown			Not Reported
Therapeutic Product Effect Incomplete; Unevaluable Event; Urticaria								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843675	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609334		71 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Dizziness;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Nausea; Vomiting	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Unknown	Not Reported
Atorvastatin Calcium	C	Unknown	Not Reported
Irbesartan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843730	EXPEDITED (15-DAY)		HO	CA-ABBVIE-20K-028-3424015-00		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Test Abnormal; Burns First Degree	Humira			S	Subcutaneous			Not Reported
	Plaquenil			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2020	17843746	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042236			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	11883803	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1687418		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Intentional Product Use Issue; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Off Label Use; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Surgery; Synovitis	Naproxen	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Leflunomide	S	Unknown	Every 2 Days	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Enbrel	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Naproxen Sodium	S	Unknown		Not Reported
	Adalimumab	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Oral		Not Reported
	Apo-Naproxen	S	Unknown		Not Reported
	Apo-Prednisone	S	Unknown		Not Reported
	Cosentyx	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Prednisone Acetate	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 731.0 Nos	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	C			Not Reported
	Folic Acid	C			Not Reported
	Celebrex	C	Unknown		Not Reported
	Metformin	C	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12222790	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-020922		83 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction;	Orencia			S	Intravenous (not	750 Milligram, Q4wk		Bristol Myers Squibb	
Arthralgia; Arthropathy;					otherwise specified)				
Blood Creatinine	Humira			S	Subcutaneous	Unk		Not Reported	
Increased; Blood	Gabapentin			S	Oral	100 Milligram, Bid		Not Reported	
Magnesium Increased;	Celebrex			S	Oral	Unk		Not Reported	
Blood Potassium	Celebrex			S	Unknown			Not Reported	
Increased; Bone Cyst;	Apo Celecoxib			S	Oral	Unk		Not Reported	
Crohn'S Disease; Cyst;	Actemra			S	Intravenous (not	488 Milligram, Qmo		Not Reported	
Deafness Neurosensory;					otherwise specified)				
Deformity; Diarrhoea;	Fentanyl			S	Unknown	Unk		Not Reported	
Drug Hypersensitivity;	Oxycontin			S	Unknown	Unk		Not Reported	
Drug Ineffective; Drug	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
Intolerance; Dry Eye;	Leflunomide			S	Oral	20 Milligram, Qd		Not Reported	
Epigastric Discomfort;	Methotrexate Sodium			S	Subcutaneous	1 Dosage Form, Qwk		Not Reported	
Exostosis; Fatigue;	Sulfasalazine			S	Oral	2.5 Gram, Qd		Not Reported	
Gastrointestinal Disorder;	Sulfasalazine			S	Oral	500 Milligram, Qd		Not Reported	
Hepatic Enzyme	Sulfasalazine			S	Oral	2.5 Milligram		Not Reported	
Increased;	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
Hypersensitivity; Infection;	Plaquenil [Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
Joint Swelling; Mobility	Phosphate]								
Decreased;	Myochrysine			S	Intramuscular	50 Milligram, Q3wk		Not Reported	
Musculoskeletal Stiffness;	Apo Gabapentin			S	Oral	100 Milligram, Bid		Not Reported	
Myocardial Infarction;	Arava			S	Oral	20 Milligram, Qd		Not Reported	
Nausea; Off Label Use;	Nortriptyline			S	Oral	10 Milligram, Qd		Not Reported	
Osteoarthritis; Osteopenia;	Hydrochloride;Perphenazine								
Osteosclerosis; Pain; Pain	Fentanyl Citrate			S	Epidural			Not Reported	
In Extremity; Pleural									
Fibrosis; Pleural									
Thickening; Presbycusis;									
Renal Impairment;									
Rheumatoid Arthritis; Skin									
Lesion; Sleep Disorder;									
Therapeutic Product Effect									
Decreased; Treatment									
Failure									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fentanyl Matrix	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
Methotrexate	S	Subcutaneous	1 Dosage Form, Qwk	Not Reported
Omega 3 [Fish Oil;Tocopherol]	C	Unknown	1200 Milligram, Bid	Not Reported
Multivitamin [Ascorbic Acid;Calcium Pantothenate;Ergocalciferol;Nico ti	C	Unknown	Unk	Not Reported
Tecta	C	Unknown	40 Mg, Qd	Not Reported
Diphenoxylate	C	Unknown	2.5 Milligram, Qd	Not Reported
Diphenoxylate	C	Unknown	1 Dosage Form, Qd	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown	400 Unit, Qd	Not Reported
Actonel	C	Unknown	36 Milligram, Qwk	Not Reported
Prednisone	C	Unknown	5 Milligram, Qd	Not Reported
Prednisone	C	Unknown	5 Milligram 1 Every 2 Hour	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q4wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Q2wk	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	750 Milligram, Qmo	Not Reported
Calcium	C	Unknown	Unk	Not Reported
Acetaminophen W/Oxycodone	C	Unknown	1 Dosage Form Prn	Not Reported
Biotin;Calcium Carbonate;Colecalciferol;Folic Acid	C	Unknown		Not Reported
Ergocalciferol	C	Unknown	400 International Unit, Qd	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Esomeprazole	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole	C	Unknown	400 Milligram, Bid	Not Reported
Ferrous Gluconate	C	Unknown	300 Milligram, Qd	Not Reported
Loperamide Hydrochloride	C	Unknown	2.5 Milligram	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pyridoxine	C	Unknown	Unk	Not Reported
Nasonex	C	Nasal	2 Dosage Form, Bid	Not Reported
Pantoprazole Magnesium	C	Unknown	40 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram, Qd	Not Reported
Trazodone Hydrochloride	C	Oral	50 Milligram 1 Every 1 Hour	Not Reported
Tylenol	C	Oral	1000 Milligram, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	1 Dosage Form, Qd	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	2.5 Milligram	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 Milligram, Bid	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	40 International Unit, Qd	Not Reported
Oxycodone Terephthalate	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid	C	Unknown	Unk Unk, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram, Bid	Not Reported
Xeljanz	C	Unknown	5 Milligram, Qd	Not Reported
Xeljanz	C	Unknown	5 Milligram	Not Reported
Vitamin B12 Aaa	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported
Biotin	C	Unknown	Unk	Not Reported
Docosahexaenoic Acid;Eicosapentaenoic Acid	C	Unknown	1200 Milligram, Bid	Not Reported
Ferrous Fumarate	C	Unknown	Unk	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Unk	Not Reported
Nicotinamide	C	Unknown	Unk	Not Reported
Retinol Palmitate	C	Unknown	Unk	Not Reported
Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Hydrochloride	C	Unknown	Unk Unk, Qd	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Trazodone	C	Unknown	Unk	Not Reported

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Vitamin A Nos	C	Unknown	Unk	Not Reported
Vitamin B 12 [Cyanocobalamin]	C	Unknown	Unk	Not Reported
Vitamin C Acid	C	Unknown	Unk	Not Reported
Nortriptyline Hydrochloride	C	Oral	10 Milligram 1 Every One Hour	Not Reported
Nexium [Esomeprazole Sodium]	C	Unknown	40 Milligram, Bid	Not Reported
Gentel [Hypromellose]	C	Unknown		Not Reported
Oxycodone Hydrochloride; Oxycodone Terephthalate; Paracetamol	C	Unknown	1 Dosage Form, As Required	Not Reported
Perphenazine	C	Unknown	40 Milligram, Qd	Not Reported
Perphenazine	C	Oral	10 Milligram	Not Reported
Percocet [Oxycodone Hydrochloride; Paracetamol]	C	Unknown	1 Dosage Form, Prn	Not Reported
Vitamin E [Tocopherol]	C	Unknown	Unk	Not Reported
Atropine Sulfate; Diphenoxylate Hydrochloride	C	Unknown	Unk	Not Reported
Celecoxib	S	Oral	Unk	Not Reported
D-Alpha Tocopherol	C	Unknown	1200 Milligram, Bid	Not Reported
Epa Dha 720	C	Unknown	Unk	Not Reported
Fergon	C	Unknown	300 Milligram, Qd	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	C	Unknown	Unk	Not Reported
Loperamide	C	Unknown		Not Reported
Omega-3 [Salmo Salar Oil]	C	Unknown	Unk	Not Reported
Omega-3 Fatty Acids	C	Unknown	1200 Milligram, Bid	Not Reported
Pantoprazole	C	Unknown	40 Milligram, Qd	Not Reported
Pantoprazole	C	Unknown	400 Milligram	Not Reported
Sodium Ascorbate	C	Unknown	Unk	Not Reported

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Sodium	C	Unknown	Unk	Not Reported
Cholecalciferol	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	1000 Milligram, Qd	Not Reported
Risedronate Sodium	C	Unknown	36 Milligram, Qwk	Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	1200 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12330313	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1750335		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Alopecia; Arthralgia; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Eruption; Drug Hypersensitivity; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance; Drug Tolerance Decreased; Erythema; Gastric Disorder; Granuloma Skin; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Musculoskeletal Stiffness;	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2, Therapy Duration: 2 Years Therapy Duration: 12 Months		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg X 2		Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S	Unknown	Therapy Duration: 10 Months		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 20 Years		Not Reported
	Enbrel			S	Unknown			Not Reported

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Pain; Panniculitis;	Enbrel	S	Unknown		Not Reported
Peripheral Swelling;	Codeine	S	Unknown		Not Reported
Product Use Issue; Rash;	Orencia	S	Unknown		Not Reported
Rash Pruritic; Red Blood	Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Cell Sedimentation Rate	Humira	S	Subcutaneous		Not Reported
Increased; Rheumatoid	Remicade	S	Intravenous (not	Therapy Duration: 365	Not Reported
Arthritis; Rheumatoid			otherwise specified)		
Nodule; Skin Necrosis;	Sulfasalazine	S	Unknown		Not Reported
Skin Ulcer; Therapeutic	Methotrexate Sodium	S	Oral	Therapy Duration: 20	Not Reported
Product Effect Decreased;				Years	
Therapeutic Product Effect	Methotrexate Sodium	S	Oral	Therapy Duration: 20	Not Reported
Incomplete; Therapeutic				Years	
Response Decreased;					
Ulcer					
	Myochrysine	S	Intramuscular		Not Reported
	Alendronic Acid	S	Unknown		Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Arava	S	Unknown		Not Reported
	Azathioprine	S	Unknown		Not Reported
	Celebrex	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Infliximab	S	Intravenous (not		Not Reported
			otherwise specified)		
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Naproxen	S	Unknown		Not Reported
	Rituximab	S	Unknown		Not Reported

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Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Tocilizumab	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Prednisolone	C	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12370677	EXPEDITED (15-DAY)		DS, HO, OT	CA-ROCHE-1756598		68 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Arthropathy; Breath Sounds Abnormal; Condition Aggravated; Contraindicated Product Administered; Hepatic Enzyme Increased; Inflammation; Joint Swelling; Loss Of Personal Independence In Daily Activities; Off Label Use; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis; Treatment Failure	Actemra			S	Subcutaneous			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Therapy Duration: 365 Nos		Not Reported
	Methotrexate Sodium			S	Unknown	Unknown Dose And Frequency, Discontinued		Not Reported
	Enbrel			S	Subcutaneous	Unknown Dose And Frequency		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Remicade			S	Intravenous (not			Not Reported

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		otherwise specified)	
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	End Date: Unknown
Apo-Leflunomide	S	Unknown	Not Reported
Apo-Leflunomide	S	Intravenous (not otherwise specified)	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Acetylsalicylic Acid	C	Unknown	Not Reported
Actonel	C	Unknown	Not Reported
Alprazolam	C	Unknown	Not Reported
Amlodipine	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Bisoprolol Fumarate	C	Unknown	Not Reported
Celebrex	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Iron Sucrose	C	Unknown	Not Reported
Metformin	C	Unknown	Not Reported
Morphine Sulfate	C	Unknown	Not Reported

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Pantoprazole	C	Unknown	Not Reported
Paroxetine	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Intracardiac	Not Reported
Risedronate	C	Unknown	Not Reported
Simponi	C	Subcutaneous	Not Reported
Simvastatin	C	Unknown	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Telmisartan	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12769617	EXPEDITED (15-DAY)		OT	CA-ROCHE-1832761			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Back Injury; Drug Ineffective; Fall; Headache; Injury; Nausea; Off Label Use; Treatment Failure; Vomiting	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

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Methotrexate	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12838058	EXPEDITED (15-DAY)		OT	CA-ROCHE-1840826		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bone Erosion; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Joint Swelling; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Synovitis; Vomiting	Actemra			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown	Solution For Injection In Pre-Filled Syringe		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydromorphone			C	Unknown			Not Reported
	Aspirin [Acetylsalicylic Acid]			C	Unknown			Not Reported
	Cymbalta			C	Unknown			Not Reported
	Synthroid			C				Not Reported
	Remicade			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12859898	EXPEDITED (15-DAY)		OT	CA-ROCHE-1695809		76 YR	Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain; Condition Aggravated; Contraindicated Product Administered; Drug Ineffective; Drug Ineffective; Fatigue; Incorrect Route Of Product Administration; Joint Swelling; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Off Label Use; Pain; Peripheral Swelling; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration 4 Months		Not Reported
	Humira			S	Subcutaneous	Therapy Duration: 7.0 Month(S)		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown	Therapy Duration: 10.0 Month(S)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Prednisone			S	Oral			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12930360	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-092641		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Hepatic Steatosis; Hypersensitivity; Oral Disorder; Rheumatoid Arthritis; Synovitis;	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported

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Transaminases Abnormal	Actemra	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous		Not Reported
	Remicade	S	Unknown		Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Desoximetasone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	12985318	EXPEDITED (15-DAY)		OT	CA-ROCHE-1859492		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Off Label Use; Synovitis; Therapeutic Response Decreased	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported

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Amitriptyline Hydrochloride	S	Unknown	Not Reported
Amitriptyline Hydrochloride	S	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Calcium Carbonate	C	Unknown	Not Reported
Cymbalta	C		Not Reported
Elavil [Amitriptyline Hydrochloride]	C	Unknown	Not Reported
Hydrochlorothiazide	C		Not Reported
Imitrex [Sumatriptan]	C		Not Reported
Lyrica	C	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Not Reported
Premarin	C		Not Reported
Tenormin	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Acetaminophen	C		Not Reported
Amitriptyline	C		Not Reported
Sumatriptan	C		Not Reported
Sumatriptan Succinate	C		Not Reported
Tofacitinib	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	13114444	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20170105843		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Adverse Event; Alanine Aminotransferase Increased; Ankylosing Spondylitis; Arthralgia; Aspartate Aminotransferase Increased; Asthenia; Asthma; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; Blood Test	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Body Temperature Decreased; Bone Lesion; C-Reactive Protein Increased;	Methotrexate Sodium	S	Subcutaneous		Not Reported
Cataract; Chest Pain; Chills; Contraindicated Product Administered; Contusion; Deep Vein Thrombosis; Diarrhoea; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Drug Tolerance Decreased; Dysphonia; Dyspnoea; Erythema; Fall; Fatigue; Feeling Abnormal; Gastrointestinal Disorder; Gastrointestinal Pain; Granuloma Skin; Heart Rate Increased; Hepatic Enzyme Abnormal; Hypercalcaemia; Hypersensitivity; Infection; Inflammation; Influenza; Infusion Related Reaction; Lethargy; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Morton'S Neuralgia; Muscular Weakness;	Methotrexate Sodium	S	Subcutaneous	Start Date: 5th Of Unspecified Month	Not Reported
Musculoskeletal Disorder; Musculoskeletal Stiffness; Mycotic Allergy; Nausea; Neuropathy Peripheral; Oral Discomfort; Pain; Pain In Extremity; Panniculitis; Peripheral Swelling; Product Use	Methotrexate Sodium	S	Subcutaneous	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate Sodium	S	Subcutaneous	Start Date: 8th Of Unspecified Month	Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Methotrexate Sodium	S	Subcutaneous		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown	Start Date: On 10th Of Unspecified Month In 2011.	Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Actemra	S	Unknown		Not Reported
	Alendronate	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral	4 Years	Not Reported
	Methotrexate	S	Oral		Not Reported



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Issue; Productive Cough; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate Increased; Respiratory Tract Congestion; Rheumatoid Arthritis; Rheumatoid Nodule; Rhinorrhoea; Skin Necrosis; Skin Ulcer; Speech Disorder; Therapeutic Response Decreased; Ulcer	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Subcutaneous		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Sulfasalazine	S	Intravenous (not otherwise specified)		Not Reported
	Codeine	S	Unknown		Not Reported
	Alendronate Sodium	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown	Start Date: 5th Of Unspecified Month	Not Reported
	Methotrexate	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Methotrexate	S	Unknown		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Parenteral		Not Reported
Myochrysine	S	Intramuscular		Not Reported
Orencia	S	Unknown	Start Date: 1st Of Unspecified Month	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Hydroxychloroquine	S	Oral		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Actemra	S	Intravenous (not otherwise specified)		Not Reported
Alendronic Acid	S			Not Reported
Arava	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported
Cosentyx	S	Subcutaneous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cosentyx	S	Subcutaneous	Not Reported
Cosentyx	S	Subcutaneous	Not Reported
Ergocalciferol	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Ciclosporin	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Xeljanz	C	Unknown	Not Reported
Prednisolone	C		Not Reported
Desoximetasona	C		Not Reported
Naproxen	C		Not Reported
Plaquenil /00072602/	C		Not Reported
Simponi	C	Subcutaneous	Not Reported
Sulfasalazine	C		Not Reported
Symbicort	C		Not Reported
Tramadol Hydrochloride	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	13772085	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091773			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Orencia			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
Adverse Event; Drug	Orencia			S	Intravenous (not	125 Milligram, Qwk		Bristol Myers Squibb
Ineffective; Foot					otherwise specified)			
Deformity; Hand	Actemra			S	Unknown	Unk		Not Reported
Deformity; Intentional	Arava			S	Oral	20 Milligram, Qd		Not Reported
Product Use Issue; Joint	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported
Swelling; Leukopenia;	Humira			S	Subcutaneous	Unk		Not Reported
Loss Of Personal	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
Independence In Daily	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram, Qd		Not Reported
Activities; Pain In	Hydroxychloroquine Phosphate			S	Unknown	400 Mg, Qd		Not Reported
Extremity; Rash;	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported
Rheumatoid Arthritis;								
Therapeutic Product Effect								
Decreased; Therapeutic								
Product Effect Incomplete;								
Toxicity To Various								

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Agents; Visual Impairment	Gold	S	Unknown	Unk	Not Reported
	Methotrexate	S	Subcutaneous	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Sodium Aurothiomalate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown	400 Milligram, Qd	Not Reported
	Sulfasalazine	S	Oral	1 G, Qd	Not Reported
	Hydroxychloroquine	S	Unknown	400 Milligram, Qd	Not Reported
	Apo-Hydroxyquine	S	Unknown	400 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Xeljanz	S	Unknown	5 Milligram, Bid	Not Reported
	Adalimumab	S	Subcutaneous	40 Milligram	Not Reported
	Solu-Medrol	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Xeljanz	C	Oral	5 Milligram, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	13854687	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-070309			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Oral	Unk		Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not	Unk		Not Reported	

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Rituxan	S	otherwise specified)	Unk	Not Reported
Hydroxychloroquine	S	Intravenous (not otherwise specified)	Unk	Not Reported
Leflunomide	S	Unknown	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	14633459	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-019566		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dependence; Drug Ineffective; Enterocolitis; Rheumatoid Factor Positive; Synovitis; X-Ray Abnormal	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Methotrexate			S	Unknown	25 Milligram		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Rituxan			S	Unknown	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15461181	EXPEDITED (15-DAY)		OT	CA-ROCHE-2190731			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Abscess; Arthralgia; Diarrhoea; Drug Ineffective; Hypoaesthesia; Impaired Work Ability; Injection Site	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported

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Reaction; Joint Swelling;	Enbrel	S	Unknown	Not Reported
Malaise; Pain; Product	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Dose Omission; Rash;	Prednisone	S	Unknown	Not Reported
Rheumatoid Arthritis;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Rheumatoid Nodule;				
Swelling; Systemic Lupus				
Erythematous Rash;	Methotrexate	S	Unknown	Not Reported
Tooth Infection; Weight				
Decreased	Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Actonel	C	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15622674	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2557515-00			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Humira			S	Subcutaneous			Not Reported	
Arthropathy; Cough; Drug	Actemra			S	Unknown			Not Reported	
Ineffective; Influenza;	Enbrel			S	Unknown			Not Reported	
Nasopharyngitis; Nausea;	Methotrexate			S	Oral			Not Reported	
Psoriasis; Rash	Plaquenil			S	Unknown			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15629653	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-18K-028-2557267-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Arthropathy;	Humira			S	Subcutaneous			Not Reported	
Contraindicated Product									

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Administered; Drug Ineffective; Liver Function Test Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Actemra	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single Use Pre-Filled Syringe	Not Reported
	Enbrel	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Etanercept	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)		Not Reported
	Imuran	C	Unknown		Not Reported
	Azathioprine	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15681461	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2575030-00		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Adverse Event; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Tofacitinib Citrate	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Aspirin	C	Unknown	Not Reported
	Cymbalta	C	Unknown	Not Reported
	Hydromorphone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Not Reported
	Orencia	C		Not Reported
	Acetylsalicylic Acid	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15802644	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2616920-00		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; C-Reactive Protein Increased;	Humira			S	Subcutaneous			Not Reported
Contraindicated Product	Actemra			S	Unknown			Not Reported
Administered; Drug	Enbrel			S	Unknown			Not Reported
Hypersensitivity; Drug	Marijuana			S	Unknown			Not Reported
Ineffective; Drug	Methotrexate			S	Unknown			Not Reported
Intolerance; Feeling	Minocycline			S	Unknown			Not Reported
Abnormal; Haemoglobin Decreased; Herpes	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zoster; Interstitial Lung Disease; Joint Swelling; Photosensitivity Reaction; Red Blood Cell Sedimentation Rate Abnormal; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Stomatitis; Urticaria	Oxycodone	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cannabis Sativa	S	Unknown	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15803741	EXPEDITED (15-DAY)		DS, OT	CA-ABBVIE-19K-028-2618078-00			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Contraindicated Product Administered; Drug Ineffective; Hepatic Cirrhosis; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celecoxib			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	15958056	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170820946		42 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Adverse Reaction; Blood Iron Abnormal; Contraindication To Vaccination; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Joint Swelling; Laryngeal Disorder; Nausea; Off Label Use; Pain; Product Use Issue; Pruritus; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete; Treatment Failure; Weight Decreased	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Simponi			S	Subcutaneous				Janssen
	Simponi			S					Janssen
	Actemra			S	Intravenous (not otherwise specified)				Not Reported
	Arava			S	Oral				Not Reported
	Ciclosporin			S	Oral				Not Reported
	Cimzia			S	Subcutaneous				Not Reported
	Enbrel			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Hydroxychloroquine			S	Oral				Not Reported
	Imuran			S	Unknown				Not Reported
	Methotrexate			S	Oral				Not Reported
	Sulfasalazine			S	Unknown				Not Reported
	Humira			S	Subcutaneous	0.8 MI			Not Reported
	Humira			S	Subcutaneous	0.8 MI			Not Reported
	Humira			S	Subcutaneous	0.8 MI			Not Reported
	Humira			S	Subcutaneous				Not Reported
	Gold			S	Unknown				Not Reported
	Plaquenil			S	Unknown				Not Reported
	Certolizumab			S	Subcutaneous				Not Reported
	Azathioprine			S	Unknown				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate Sodium	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Certolizumab Pegol	S	Unknown	Not Reported
Lyrica	S	Oral	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Infliximab	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Cellcept /01275102/	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Piroxicam	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Xeljanz	C	Oral	Not Reported
Leflunomide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	16189081	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011205		24 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clear Cell Renal Cell Carcinoma; Diarrhoea; Renal Mass; Vomiting	Amitriptyline			S	Unknown			Apotex
	Naproxen Sodium			S	Unknown	Unk		Apotex
	Azathioprine			S	Unknown			Apotex
	Cyclosporine			S	Unknown			Apotex
	Folic Acid			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Leflunomide	S	Unknown		Apotex
Oxycodone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Medroxyprogesterone	S	Unknown	Unk	Not Reported
Depo-Provera	S	Unknown		Not Reported
Etanercept	S	Unknown	25 Mg, Q.Wk.	Not Reported
Infliximab	S	Unknown	400 Mg, Total	Not Reported
Methotrexate	S	Unknown		Not Reported
Naprosyn /00256201/	S	Unknown		Not Reported
Rituximab	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Anakinra	C	Unknown	Unk	Not Reported
Cyclosporine	C	Unknown	Unk	Not Reported
Depo-Provera	C	Unknown	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	16480475	EXPEDITED (15-DAY)		OT	US-MALLINCKRODT-T201804782			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Arthralgia;	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 MI, 1 Time Weekly Sunday		Mallinckrodt	
Arthritis; Back Pain; Blood Cholesterol Abnormal;	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 MI, 1 Time Weekly Sunday		Mallinckrodt	
Blood Sodium Increased; Blood Uric Acid Increased;	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 MI, 1 Time Weekly (Sunday)		Mallinckrodt	
Chest Pain; Depression; Dizziness; Eye	Repository Corticotropin Injection			S	Subcutaneous	80 Units/1 MI, 1 Time Weekly (Sunday)		Mallinckrodt	
Haemorrhage; Fatigue; Gait Disturbance;	Repository Corticotropin Injection			S	Unknown	40 Units/1 MI		Mallinckrodt	
Headache; Heart Rate Increased; Hyperhidrosis;	Repository Corticotropin Injection			S	Subcutaneous	40 Units/0.5 MI, 1 Time		Mallinckrodt	
Hypertension; Hypoaesthesia; Immune	Repository Corticotropin Injection								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

System Disorder; Infection; Influenza; Insomnia; Malaise; Memory Impairment; Menorrhagia; Mental Fatigue; Mobility Decreased; Mood Altered; Muscle Spasms; Muscular Weakness; Musculoskeletal Pain; Nausea; Neck Pain; Nervousness; Pain; Pain In Extremity; Pallor; Papilloedema; Poisoning; Polymenorrhoea; Product Dose Omission; Proteinuria; Renal Impairment; Sciatica; Sensitivity To Weather Change; Somnolence; Stress; Systemic Lupus Erythematosus; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Repository Corticotropin Injection Repository Corticotropin Injection Repository Corticotropin Injection Plaquenil Prednisone Prednisone Prednisone Prednisone Cellcept Benlysta	S S S S C C C C C C C	Subcutaneous Subcutaneous Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown	Weekly (Sunday) 40 Units / 0.5 MI, 1 Time Weekly, Sunday 80 Units / 1 MI, 1 Time Weekly, Sunday 40 Units Once Weekly Unk Unk 5 Mg, Unk Unk, Every Other Day Unk, Once A Day Unk	Mallinckrodt Mallinckrodt Mallinckrodt Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	16561502	EXPEDITED (15-DAY)		OT	CA-ROCHE-2351627		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Injury;	Actemra			S	Unknown			Not Reported
Back Pain; Discomfort;	Apo-Prednisone			S	Unknown			Not Reported
Drug Hypersensitivity;	Arava			S	Unknown			Not Reported
Drug Ineffective;	Enbrel			S	Unknown			Not Reported
Intervertebral Disc Compression;	Hydroxychloroquine			S	Unknown			Not Reported
Intervertebral Disc Space Narrowing; Joint Stiffness;	Methotrexate			S	Unknown			Not Reported
Joint Swelling; Malaise; Musculoskeletal Pain;	Methotrexate			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Nausea; Neck Pain; Pain; Peripheral Swelling; Scoliosis; Spinal Disorder; Spinal Stenosis; Swelling; Therapeutic Response Decreased

Simponi

S Subcutaneous

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	16617646	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190717471		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Alanine Amino transferase Increased; Arthralgia; Aspartate Amino transferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Chills; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Tolerance Decreased; Granuloma Skin; Headache; Hepatic Enzyme Increased; Hypercalcaemia; Hypersensitivity; Inflammation; Infusion Related Reaction; Joint Swelling; Liver Disorder; Loss Of Personal Independence In Daily Activities; Mesenteritis; Nausea; Oedema Peripheral; Off Label Use; Panniculitis; Peripheral	Remicade Actemra Actemra Alendronate Apo-Hydroxyquine Leflunomide Codeine Enbrel Enbrel Enbrel Humira Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate Methotrexate			S S S S S S S S S S S S S S S S S S S S		Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Subcutaneous Subcutaneous Subcutaneous Subcutaneous Unknown Unknown Subcutaneous Unknown Unknown Subcutaneous Unknown Unknown		Janssen Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling; Pyrexia; Rash;	Orencia	S	Unknown	Not Reported
Rash Pruritic; Rheumatoid	Orencia	S	Unknown	Not Reported
Arthritis; Rheumatoid	Rituximab	S	Intravenous drip	Not Reported
Nodule; Skin Necrosis;	Sulfasalazine	S	Unknown	Not Reported
Skin Ulcer; Ulcer	Desoximetasone	S	Unknown	Not Reported
	Tocilizumab	S	Intravenous (not otherwise specified)	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Methotrexate	S	Oral	Not Reported
	Prednisone	C	Unknown	Not Reported
	Xeljanz	C	Unknown	Not Reported
	Ciclosporin	C	Unknown	Not Reported
	Alendronate Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17121205	EXPEDITED (15-DAY)		OT	US-UCBSA-2017020170			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Cimzia			S		Unk		Not Reported
Headache; Pruritus; Rash;	Methotrexate			S	Oral	20 Mg, Weekly (Qw)		Not Reported
Rheumatoid Arthritis	Enbrel			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Folic Acid			C	Oral	3 Mg, Once Daily (Qd)		Not Reported
	Nexium			C	Oral	20 Mg Daily		Not Reported
	Tofacitinib			C	Oral	11 Mg, Once Daily (Qd)		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17183725	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019543728			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Diabetes Mellitus; Drug Ineffective; Flank Pain; Lymphoma; Neutrophil Count Increased; Splenomegaly; White Blood Cell Count Increased; White Blood Cell Disorder	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported	
	Cortisone			C	Intramuscular	Unk, As Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17245688	EXPEDITED (15-DAY)		OT	CA-ROCHE-2512708		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Desoximetasone			S	Oral			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Subcutaneous	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Hydroxychloroquine Phosphate	S	Unknown	Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17260299	EXPEDITED (15-DAY)		OT	CA-ROCHE-2516104			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Contraindicated	Rituxan			S	Intravenous drip			Not Reported
Product Administered;	Arava			S	Unknown			Not Reported
Drug Ineffective;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Glossodynia; Maternal	Cimzia			S	Subcutaneous			Not Reported
Exposure During	Cortisone Acetate			S	Unknown			Not Reported
Pregnancy; Pain;	Diclofenac			S	Unknown			Not Reported
Pemphigus; Product Use	Enbrel			S	Subcutaneous			Not Reported
Issue; Rheumatoid	Folic Acid			S	Unknown			Not Reported
Arthritis; Systemic Lupus	Fosamax			S	Unknown			Not Reported
Erythematosis	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous bolus	Not Reported
Simponi	S	Subcutaneous	Not Reported
Tocilizumab	S	Unknown	Not Reported
Etanercept	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17266000	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-2516492		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Subcutaneous			Not Reported
Alopecia; Anti-Cyclic Citrullinated Peptide Antibody Positive;	Rituxan			S	Intravenous (not otherwise specified)	365		Not Reported
Arthropathy; Condition Aggravated;	Apo-Folic Acid			S	Unknown			Not Reported
Contraindicated Product	Apo-Hydroxyquine			S	Unknown			Not Reported
Administered; Discomfort;	Apo-Prednisone			S	Unknown			Not Reported
Drug Ineffective; Drug Intolerance; Duodenal	Apo-Prednisone			S	Unknown			Not Reported
Ulcer Perforation; Fatigue;	Arava			S	Oral			Not Reported
Glossodynia; Hand Deformity; Helicobacter	Cetirizine Hydrochloride			S	Unknown			Not Reported
Infection; Hepatic Enzyme Increased; Hip	Cetirizine Hydrochloride			S	Unknown			Not Reported
Arthroplasty;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Hypersensitivity; Infusion	Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Related Reaction; Joint Swelling; Knee Arthroplasty; Pain; Pemphigus; Pericarditis; Pregnancy; Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous	Single-Use Prefilled Syringe	Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Cortisone Acetate	S	Topical		Not Reported
	Desoximetasone	S	Oral		Not Reported
	Desoximetasone	S	Cutaneous		Not Reported
	Desoximetasone	S	Unknown		Not Reported
	Diclofenac Sodium	S	Unknown		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Oral		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine	S	Oral		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Methotrexate	S	Oral		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Orencia	S	Intravenous (not otherwise specified)	365	Not Reported
	Phthalylsulfathiazole	S	Unknown		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Prednisone	S	Oral	365.0	Not Reported
	Prednisone	S	Unknown		Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
	Remicade	S	Intravenous (not		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Simponi	S	Subcutaneous			Not Reported
Sulfasalazine	S	Oral	365.0		Not Reported
Sulfasalazine	S	Oral	365.0		Not Reported
Sulfathalidine	S	Unknown			Not Reported
Tofacitinib Citrate	S	Unknown			Not Reported
Topicort [Desoximetasone]	S	Cutaneous			Not Reported
Actemra	S	Unknown			Not Reported
Sarilumab	S	Unknown			Not Reported
Hydrocortisone Acetate	S	Subcutaneous			Not Reported
Hydrocortisone Acetate	S	Cutaneous			Not Reported
Paracetamol	S	Unknown			Not Reported
Cortisone	S	Oral			Not Reported
Xeljanz	S	Unknown			Not Reported
Salazopyrin	C				Not Reported
Leflunomide	C	Unknown			Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17336937	EXPEDITED (15-DAY)		OT	CA-ROCHE-2530816			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Unknown			Not Reported
	Etanercept			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Prednisone	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17370571	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2533713			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency; Antibody Test Positive; Arthritis; Body Height Below Normal; Bone Density Decreased; C-Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Drug Intolerance; Human Antichimeric Antibody Positive; Juvenile Idiopathic Arthritis; Loss	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported
	Infliximab			S	Unknown			Not Reported
	Kineret			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Naproxen			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Of Personal Independence In Daily Activities; Obesity; Off Label Use;	Orencia	S	Intravenous (not otherwise specified)	Not Reported
Polyarthrititis; Psoriasis;	Prednisone	S	Oral	Not Reported
Red Blood Cell Sedimentation Rate	Prednisone	S	Oral	Not Reported
Increased; Septic Shock;	Sulfasalazine	S	Oral	Not Reported
Synovitis; Vomiting	Triamcinolone	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Immunoglobulin Human Normal	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17397440	EXPEDITED (15-DAY)		OT	CA-UCBSA-2017050946		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Prescribed	Cimzia			S	Subcutaneous	Unk		Not Reported
Underdose; Rheumatoid Arthritis; Therapeutic	Actemra			S				Not Reported
Product Effect Incomplete	Anakinra			S		100 Mg, Unk		Not Reported
	Celebrex			S		200 Milligram		Not Reported
	Celebrex			S				Not Reported
	Celebrex			S		Unk		Not Reported
	Celebrex			S				Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Subcutaneous	1 Ml, Weekly (Qw)		Not Reported
	Plaquenil			S				Not Reported
	Apo-Prednisone			S		7 Mg, Once Daily (Qd)		Not Reported
	Apo-Leflunomide			S	Oral	10 Milligram, Once Daily (Qd)		Not Reported
	Apo-Leflunomide			S	Oral	20 Milligram, Once Daily (Qd)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	7 Milligram, Once Daily (Qd); Powder For Solution Intravenous		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Solution	Not Reported
Xeljanz	S	Oral	5 Milligram, 2x/Day (Bid)	Not Reported
Hydroxychloroquine	S		300 Milligram, Once Daily (Qd)	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Sulfasalazine	S		500 Milligram	Not Reported
Apo-Azathioprine	S		Unk	Not Reported
Arava	S			Not Reported
Prednisone	S		7 Milligram, Once Daily (Qd)	Not Reported
Hydroxychloroquine Sulfate	S			Not Reported
Orencia	S	Intravenous (not otherwise specified)	0.75 Milligram, Monthly (Qm)	Not Reported
Celecoxib	S		Unk	Not Reported
Celecoxib	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Azathioprine	S		Unk	Not Reported
Acetaminophen And Codeine Phosphate	C		Unk	Not Reported
Altace	C		5 Milligram	Not Reported
Altace	C		10 Milligram	Not Reported
Apo-Gabapentin	C	Oral	100 Milligram	Not Reported
Apo-Gabapentin	C		300 Milligram	Not Reported
Atorvastatin Calcium	C	Oral	40 Milligram, Once Daily (Qd)	Not Reported
Atorvastatin Calcium	C		40 Milligram, Once Daily (Qd)	Not Reported
Cipralext [Escitalopram]	C		Unk	Not Reported
Hydromorphone Hcl	C	Oral	30 Milligram, 2x/Day (Bid)	Not Reported
Mupirocin	C	Topical	Unk	Not Reported
Pantoloc [Pantoprazole]	C		20 Milligram, Once Daily	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Shark Liver Oil	C	(Qd)	Not Reported
Tapentadol Hydrochloride	C	Unk	Not Reported
Taro-Mupirocin	C	50 Milligram	Not Reported
Tramacet	C	Topical	Not Reported
Tramadol Hydrochloride	C	Oral	Not Reported
	C	Oral	50 Milligram

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17454584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555257		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Irritable Bowel Syndrome; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Off Label Use; Stress	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Advil [Ibuprofen]			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetaminophen

C

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17457814	EXPEDITED (15-DAY)		HO	CA-UCBSA-2020007174		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Interstitial Lung Disease; Rheumatoid Arthritis	Cimzia			S	Subcutaneous	Unk		Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Subcutaneous	100 Milligram		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Mycophenolate Mofetil			S		Unk		Not Reported
	Orencia			S		Unk		Not Reported
	Apo-Leflunomide			S		Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Leflunomide			S		Unk		Not Reported
	Humira			C	Subcutaneous			Not Reported
	Celebrex			C				Not Reported
	Methotrexate			C		1 Milligram, Weekly (Qw)		Not Reported
Prednisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17464142	EXPEDITED (15-DAY)		OT	CA-ROCHE-2553858			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Contraindicated Product Administered; Drug Ineffective; Drug	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Lymphoma; Neoplasm Malignant; Off Label Use; Onychoclasia; Tooth Loss	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Zostavax	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Subcutaneous	Not Reported
	Cortisone Acetate	C	Subcutaneous	Not Reported
	Desoximetasone	C	Oral	Not Reported
	Diclofenac	C	Unknown	Not Reported
	Xeljanz	C	Oral	Not Reported
	Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17567657	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022553		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Pustular Psoriasis; Rheumatoid Arthritis; Scar; Vomiting	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Unknown	50.0 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Unk	Not Reported
Simponi	S	Subcutaneous	Unk	Not Reported
Sulfasalazine	S	Unknown	Unk	Not Reported
Tofacitinib Citrate	S	Oral	5.0 Milligram 2 Every 1 Days	Not Reported
Xeljanz	S	Unknown	5.0 Milligram 2 Every 1 Days	Not Reported
Aspirin [Acetylsalicylic Acid]	C	Unknown		Not Reported
Cymbalta	C	Unknown		Not Reported
Hydromorphone	C	Unknown		Not Reported
Remicade	C	Intravenous (not otherwise specified)		Not Reported
Synthroid	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17578950	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-024375			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Malaise; Rheumatoid Arthritis; Somnolence; Visual Impairment	Orencia			S	Unknown			Bristol Myers Squibb
	Acetaminophen			S	Unknown			Not Reported
	Actemra			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	20 Milligram, Qd		Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown	50 Milligram, Qwk		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram, Bid		Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Oral	2000 Milligram	Not Reported
Synthroid	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Meloxicam	C	Unknown		Not Reported
Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17601685	EXPEDITED (15-DAY)		OT	FR-ADVANSZ PHARMA-202003002044			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Abnormal; Burning Sensation; Constipation; Expired Product Administered; Gait Disturbance; Intentional Product Misuse; Malaise; Off Label Use; Paronychia; Skin Plaque; Systemic Lupus Erythematosus	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	2 Dosage Form, Bid (One In Morning And One In Evening, Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	3 Dosage Form (Film-Coated Tablet)		Concordia
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S				Concordia
	Amoxlcillin Trihydrate/Potassium Clavulanate			S	Unknown	Unk		Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Amoxlcillin Trihydrate/Potassium Clavulanate			S				Not Reported
	Lercan			C		10 Mg		Not Reported
	Quinine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17614338	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP009150			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Levofloxacin			S	Unknown	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin	S	Unknown	250 Mg, Qd	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Benadryl /00000402/	S	Unknown	Unk	Not Reported
	Celebrex	S	Oral	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Pms Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
	Procytox	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Procytox	S	Unknown	2000 Mg, Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Ezetrol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17648477	EXPEDITED (15-DAY)		DS, HO, LT, OT	SK-VALIDUS PHARMACEUTICALS LLC-SK- 2020VAL000270			Unknown	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Metoprolol Tartrate			S	Transplacental	Unk		Validus	
	Cefotaxime Sodium			S	Transplacental	Unk		Validus	
	Cefotaxime Sodium			S	Transplacental	Unk		Validus	

**FDA Adverse Event Reporting System
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Dexamethasone	S	Transplacental	Unk	Not Reported
Dexamethasone	S	Transplacental	Unk	Not Reported
Cefixime	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Prednisone	S	Transplacental	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Transplacental	Unk	Not Reported
Paracetamol	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Methylprednisolone	S	Transplacental	Unk	Not Reported
Omeprazole	S	Transplacental	Unk	Not Reported
Magnesium Lactate	S	Transplacental	Unk	Not Reported
Calcium Carbonate	S	Transplacental	Unk	Not Reported
Bisoprolol Fumarate	S	Transplacental	Unk	Not Reported
Fluconazole	S	Transplacental	Unk	Not Reported
Hydrocortisone	S	Transplacental	Unk	Not Reported
Potassium Chloride	S	Transplacental	Unk	Not Reported
Benzylpenicillin Sodium	S	Transplacental	Unk	Not Reported
Colecalciferol	S	Transplacental	Unk	Not Reported
Cefazolin Sodium	S	Transplacental	Unk	Not Reported
Albumin (Human)	S	Transplacental	Unk	Not Reported
Vitamin B Complex	S	Transplacental	Unk	Not Reported
Aminomethylbenzoic Acid	S	Transplacental	Unk	Not Reported
Flebogamma Dif /00025201/	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Privigen	S	Transplacental	Unk	Not Reported
Bisulepin	S	Transplacental	Unk	Not Reported
Folic Acid	S	Transplacental	Unk	Not Reported
Etamsylate	S	Transplacental	Unk	Not Reported
Nadroparine	S	Transplacental	Unk	Not Reported

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Ornidazole	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17706132	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20160600414			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Ineffective; Drug Intolerance; Off Label Use; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Simponi			S	Subcutaneous			Janssen
	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil /00072602/			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
Prednisone			C	Unknown			Not Reported	
Piroxicam			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17717838	EXPEDITED (15-DAY)		OT	CA-ROCHE-2589516			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Drug Ineffective; Spinal Compression Fracture	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17767050	EXPEDITED (15-DAY)		HO, LT, OT	JP-FERRINGPH-2020FE02993		41 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Disorder; Exposure During Pregnancy; Hormone Level Abnormal; Hypogonadism; Infarction; Pelvic Infection; Placenta Accreta; Pre-Eclampsia; Vaginal Haemorrhage	Lutinus			S	Vaginal	300 Mg, Daily		Ferring	
	Estradiol			S	Transdermal			Not Reported	
	Tacrolimus Monohydrate			S	Unknown	4 Mg		Not Reported	
	Dydrogesterone			S	Oral	15 Mg, 1 Time Daily		Not Reported	
	Prednisolone			S	Unknown	7.5 Mg		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17769919	EXPEDITED (15-DAY)		OT	CA-ROCHE-2596223			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	C		Not Reported
Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17770941	EXPEDITED (15-DAY)		OT	CA-ROCHE-2591746		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Arthralgia;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Arthritis; Blood Cholesterol Increased; C-Reactive Protein Increased;	Rituximab			S	Intravenous drip			Not Reported
Condition Aggravated;	Arava			S	Unknown			Not Reported
Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Fibromyalgia;	Enbrel			S	Unknown			Not Reported
Herpes Zoster; Infection;	Enbrel			S	Subcutaneous			Not Reported
Joint Swelling;	Enbrel			S	Unknown			Not Reported
Leukopenia; Liver Function Test Abnormal;	Gold			S	Unknown			Not Reported
Off Label Use; Oral Pain;	Humira			S	Subcutaneous			Not Reported
Peripheral Swelling;	Humira			S	Subcutaneous			Not Reported
Pneumonia Viral; Product Use Issue; Rheumatoid Arthritis; Soft Tissue Disorder; Soft Tissue Swelling; Stomatitis;	Hydroxychloroquine			S	Unknown			Not Reported
Swelling; Synovitis;	Hydroxychloroquine			S	Unknown			Not Reported
Tenderness; Therapeutic Product Effect Incomplete	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Vaginal	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Xeljanz	S	Unknown	Not Reported
Actemra	S	Unknown	Not Reported
Acetaminophen	C		Not Reported
Anakinra	C	Unknown	Not Reported
Anakinra	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C		Not Reported
Codeine	C		Not Reported
Cortisone	C	Intramuscular	Not Reported
Cortisone	C	Oral	Not Reported
Darifenacin Hydrobromide	C	Unknown	Not Reported
Darifenacin Hydrobromide	C	Oral	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Intra-articular	Not Reported
Desoximetasone	C	Intramuscular	Not Reported
Desoximetasone	C	Oral	Not Reported
Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Dexamethasone	C		Not Reported

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Dilaudid	C		Not Reported
Diphenhydramine	C		Not Reported
Diphenhydramine Hydrochloride	C	Unknown	Not Reported
Dyclone	C		Not Reported
Furosemide	C		Not Reported
Hydromorphone	C		Not Reported
Kadian	C		Not Reported
Kenalog [Triamcinolone Acetonide]	C		Not Reported
Lasix [Furosemide]	C		Not Reported
Leflunomide	C		Not Reported
Loperamide	C		Not Reported
Morphine Sulfate	C		Not Reported
Norflex [Orphenadrine Citrate]	C		Not Reported
Omnaris	C		Not Reported
Orencia	C		Not Reported
Orphenadrine	C		Not Reported
Orphenadrine Citrate	C		Not Reported
Oxyneo	C		Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Pantoprazole	C		Not Reported
Pantoprazole Sodium Anhydrous	C		Not Reported
Plantago Ovata	C		Not Reported
Restasis	C		Not Reported
Sodium Aurothiomalate	C		Not Reported
Synthroid	C		Not Reported
Triamcinolone Acetonide	C		Not Reported
Trimethoprim	C		Not Reported
Urispas	C		Not Reported
Vagifem	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17806211	EXPEDITED (15-DAY)		OT	CA-ROCHE-2599022			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intestinal Perforation; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17816647	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200514277			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Hepatic Enzyme Increased; Nausea	Remicade			S	Intravenous (not otherwise specified)			Janssen
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17817135	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020202096		82 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg		Not Reported
	Kaletra E M			S	Oral	2 Df, 2x/Day (Each 12h)		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Enalapril/Hydrochlorothiazide			C	Oral			Not Reported

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Omeprazole			C	Oral	20 Mg, 2x/Day (Each 12h)			Not Reported	
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01-Jun-2020	17835075	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204780		73 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Electrocardiogram Qt Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Reuquinol			S		400 Mg, 2x/Day Every 12 Hours Before Sleep		Not Reported	
	Reuquinol			S		400 Mg, 1x/Day		Not Reported	
	Oseltamivir			C		75 Mg, 2x/Day		Not Reported	
	Oseltamivir			C		75 Mg, 1x/Day		Not Reported	
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 4x/Day Every 6 Hours		Not Reported	
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 3x/Day Every 8 Hours		Not Reported	
	Sodium Bicarbonate			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day Every 8 Hours		Not Reported	
	Potassium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Sodium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Cortisonal [Hydrocortisone]			C	Intravenous (not otherwise specified)	100 Mg, 2x/Day Every 12 Hours		Not Reported	
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed		Not Reported	
	Encrise			C	Intravenous (not otherwise specified)	20 Iu, As Needed		Not Reported	
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Ug, As Needed		Not Reported	

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Norepinefrine	C	Intravenous (not otherwise specified)	32 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Hepamax S	C		Unk	Not Reported
Novalgina	C	Intravenous (not otherwise specified)	1 G, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17840976	EXPEDITED (15-DAY)	HO		IT-TEVA-2020-IT-1240829		77 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Injury; Off Label Use; Pruritus; Purpura; Rash	Azithromycin			S	Oral	1 Dosage Forms		Not Reported	
	Plaquenil			S	Oral	400 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17843980	EXPEDITED (15-DAY)	OT		CA-APOTEX-2020AP011163		63 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Blood Pressure Increased;	Amlodipine			S	Oral	5 Mg, Qd		Apotex	
Colitis; Dental Caries;	Amlodipine			S	Oral	Unk, Qd		Apotex	
Diabetes Mellitus	Gliclazide			S	Unknown	Unk		Not Reported	
Inadequate Control; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance;	Leflunomide			S	Unknown	Unk		Apotex	
Gastrointestinal Disorder; Haematochezia;	Asacol			S	Unknown	800 Mg, Tid		Not Reported	
Hypertension;	Diamicron			S	Unknown	Unk		Not Reported	
Musculoskeletal Stiffness; Pain In Extremity;	Enbrel			S	Subcutaneous	50 Mg, Unk		Not Reported	
Peripheral Swelling;	Humira			S	Subcutaneous	Unk		Not Reported	
Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported	
Vitamin D Deficiency;	Orencia			S	Unknown	Unk		Not Reported	
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported	

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Weight Increased	Rituxan	S	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Acetaminophen	C	Oral	650 Mg, Unk	Not Reported
	Amlodipine Besilate	C	Unknown	Unk	Not Reported
	Atacand Plus	C	Unknown	Unk	Not Reported
	Bisoprolol Fumarate	C	Unknown	Unk	Not Reported
	Crestor	C	Unknown	Unk	Not Reported
	Depo-Medrol	C	Intra-articular	Unk	Not Reported
	Diphenhydramine	C	Oral	50.0 Mg, Unk	Not Reported
	Ebastine	C	Unknown	Unk	Not Reported
	Ferrous Gluconate	C	Unknown	Unk	Not Reported
	Folic Acid	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Tylenol /00020001/	C	Unknown	Unk	Not Reported
	Vitamin D3	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844014	EXPEDITED (15-DAY)	HO		CA-ROCHE-2606464		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; C-Reactive Protein	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Abnormal; C-Reactive Protein Increased;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Condition Aggravated;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
Drug Hypersensitivity;	Apo-Leflunomide			S	Unknown			Not Reported
Drug Ineffective; Hepatic Enzyme Increased;	Arava			S	Unknown			Not Reported
Hypertension; Joint Swelling; Loss Of Personal Independence In Daily Activities;	Enbrel			S	Unknown			Not Reported

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Osteoarthritis; Pneumonia; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Increased;	Enbrel	S	Subcutaneous	Not Reported
Rheumatoid Arthritis; Rheumatoid Factor Positive; Synovitis; Therapeutic Product Effect Incomplete; Treatment Failure	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Zinc Citrate	C	Unknown	Not Reported
	Atorvastatin	C	Unknown	Not Reported
	Atorvastatin Calcium	C	Unknown	Not Reported
	Bisoprolol	C	Unknown	Not Reported
	Digoxin	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Furosemide Sodium	C	Unknown	Not Reported
	Gold	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Hydroxychloroquine	C	Unknown	Not Reported
	Leflunomide	C	Unknown	Not Reported
	Lyrica	C	Unknown	Not Reported
	Naproxen	C	Unknown	Not Reported
	Nifedipine	C	Unknown	Not Reported

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Palafer	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported
Toloxin [Digoxin]	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Vitamin D3	C	Unknown	Not Reported
Xarelto	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844059	EXPEDITED (15-DAY)	HO		CA-ROCHE-2609912		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Infection; Limb Discomfort; Rash	Cefazolin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844091	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-042281			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	40 Milligram		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844304	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605582			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; C- Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hepatic Enzyme Increased; Infection; Inflammation; Interstitial Lung Disease; Joint Injury; Joint Swelling; Loss Of Personal Independence In Daily Activities; Mobility Decreased	Actemra			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Apo-Naproxen			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous	Duration: 631.0 Days		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous	Duration: 631.0 Days		Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Duration: 631.0 Days	Not Reported
Hydroxychloroquine	S			Not Reported
Hydroxychloroquine Sulfate	S	Oral	Duration: 631.0 Days	Not Reported
Leflunomide	S	Oral	Duration: 631.0 Days	Not Reported
Leflunomide	S			Not Reported
Methotrexate	S	Unknown	Duration: 631.0 Days	Not Reported
Naproxen	S	Unknown	Duration: 631.0 Days	Not Reported
Naproxen	S	Unknown	Duration: 631.0 Days	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Duration 7 Yaers	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Sulfasalazine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844330	EXPEDITED (15-DAY)		DS, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-042253			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Ineffective; Hepatic Cirrhosis; Loss Of Personal Independence In Daily Activities	Orencia			S	Unknown			Bristol Myers Squibb	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Celecoxib			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Actemra			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone			C		Unknown		2 Milligram, Qd		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844331	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-248768		42 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Milligram, Daily		Sun	
	Hydroxyzine			S	Intravenous (not otherwise specified)	25 Milligram, Qid		Not Reported	
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	200 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844526	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606128		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Off Label Use; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	3.0 Years		Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844569	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606231		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort;	Actemra	S	Unknown	Not Reported
Alopecia; Arthralgia;	Rituxan	S	Intravenous (not	Not Reported
Contraindicated Product			otherwise specified)	
Administered; Drug	Arava	S	Unknown	Not Reported
Ineffective;	Cetirizine Hydrochloride	S	Unknown	Not Reported
Hypersensitivity; Joint	Cetirizine Hydrochloride	S	Unknown	Not Reported
Swelling; Maternal	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Exposure During	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Pregnancy;	Cimzia	S	Subcutaneous	Not Reported
Musculoskeletal Stiffness;	Cortisone Acetate	S	Unknown	Not Reported
Pain; Pemphigus;	Desoximetasone	S	Oral	Not Reported
Pericarditis; Product Use	Enbrel	S	Subcutaneous	Not Reported
Issue; Rheumatoid	Folic Acid	S	Unknown	Not Reported
Arthritis; Systemic Lupus	Folic Acid	S	Unknown	Not Reported
Erythematosis;	Golimumab	S	Unknown	Not Reported
Therapeutic Product Effect	Humira	S	Subcutaneous	Not Reported
Decreased; Treatment	Hydroxychloroquine	S	Unknown	Not Reported
Failure	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not	Not Reported
			otherwise specified)	
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported
	Sulfate]			
	Plaquenil [Hydroxychloroquine	S	Unknown	Not Reported
	Sulfate]			
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported

FDA Adverse Event Reporting System

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Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Diclofenac	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844590	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606292		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Contraindicated Product Administered; Diarrhoea; Drug Ineffective; Fatigue; Hepatic Enzyme Increased; Pneumonia; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Aleve			C				Not Reported	
	Arava			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Simponi			C	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844598	EXPEDITED (15-DAY)		OT	CA-ROCHE-2604929		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Animal Bite; Drug Ineffective; Emotional Disorder; Herpes Zoster; Inappropriate Schedule Of Product Administration; Malignant Melanoma; Mobility Decreased; Product Dose Omission; Victim Of Crime	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Oral			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Folic Acid			C				Not Reported	
	Prednisone			C	Oral			Not Reported	
	Restasis			C	Unknown			Not Reported	
	Sulfasalazine			C	Oral			Not Reported	
	Synthroid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844794	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609327		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Body Height Decreased; Drug Ineffective; Flushing; Inflammation; Intentional Product Use Issue	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	

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Simponi	S	Intravenous (not otherwise specified)	Not Reported
Xeljanz	S	Unknown	Not Reported
Acetaminophen	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Esomeprazole Sodium	C	Unknown	Not Reported
Lumigan Rc	C	Ophthalmic	Not Reported
Lyrica	C	Unknown	Not Reported
Sulfasalazin	C	Unknown	Not Reported
Pseudoephedrine Hydrochloride	C	Unknown	Not Reported
Trazodone	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported
Wellbutrin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844809	EXPEDITED (15-DAY)		DS, OT	CA-UCBSA-2020021835		42 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Condition Aggravated; Depressed Mood; Disability; Hand Deformity; Inappropriate Schedule Of Product Administration; Inflammation; Limb Discomfort; Maternal Exposure During Pregnancy; Memory Impairment; Movement Disorder; Musculoskeletal Stiffness; Nasopharyngitis; Peripheral Swelling	Cimzia			S	Subcutaneous	Unk		Not Reported
	Azathioprine			S				Not Reported
	Hydroxychloroquine Sulfate			S				Not Reported
	Methotrexate			S				Not Reported
	Acetaminophen			C				Not Reported
	Amitriptyline			C		10 Milligram, Once Daily (Qd)		Not Reported
	Azithromycin			C				Not Reported
	Domperidone			C		3 Dosage Form		Not Reported
	Esomeprazole Sodium			C		20 Milligram		Not Reported
	Gabapentin			C		400 Milligram, Once Daily (Qd)		Not Reported
	Metonia			C		5 Milligram		Not Reported
	Prednisone			C		8 Milligram, Once Daily		Not Reported

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Ranitidine	C		(Qd)	
Xeljanz	C	Oral	Unk	Not Reported
			5 Milligram, Once Daily (Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844813	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606377			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Topical			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Alendronate Sodium			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Folic Acid			S	Subcutaneous			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Simponi			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Sulfasalazine		S	Unknown				Not Reported	
	Topicort [Desoximetasone]		S	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844833	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001- 20-025			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Lymphopenia	Prednisone			S	Unknown			Westward	
	Azathioprine			S	Unknown			Westward	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844865	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606554			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Diclofenac Sodium			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	

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Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844869	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606387		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Deformity; Drug Ineffective; Dyspnoea; Gait Disturbance; Hand Deformity; Injection Site Reaction; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Sciatica	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Apo-Ramipril			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844876	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608720		43 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Drug Ineffective; Impaired Work Ability; Infection; Mobility Decreased; Off Label Use; Pain; Rheumatoid Arthritis; Sleep Disorder; Therapy Partial Responder	Actemra	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844893	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605361			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Gastrointestinal Disorder; Immobile; Lymphadenopathy; Lymphoedema; Off Label Use; Rheumatoid Arthritis; Soft Tissue Swelling	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Oral	Not Reported
Myochrysine	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sodium Aurothiomalate	S	Intramuscular	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844913	EXPEDITED (15-DAY)	OT		CA-ROCHE-2610701		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Pain; Pemphigus; Swelling; Systemic Lupus Erythematousus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Hydroxychloroquine Phosphate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844947	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-02444		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Dry Skin; Sexual Dysfunction	Triamcinolone Acetonide			S		5 Milligram Per Millilitre, Every 6 To 8 Weeks		Lupin	
	Triamcinolone Acetonide			S				Lupin	
	Finasteride			S	Oral	1.25 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Lupin	
	Isotretinoin			S	Oral	30 Milligram, Qd		Not Reported	
	Isotretinoin			S	Topical	30 Milligram, Qod		Not Reported	
	Tacrolimus			C	Topical	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17844977	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606882			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Arthritis; Rheumatoid	Actemra			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Anakinra			S	Oral			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous	Single Use Pre-Filled Syringe		Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Factor Positive; Synovitis	Gold	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Risedronate Sodium	S	Oral	Not Reported
	Risedronic Acid	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Risedronate Sodium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845025	EXPEDITED (15-DAY)		HO	CA-ROCHE-2609928			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product	Rituximab			S	Unknown			Not Reported
Administered; Drug	Enbrel			S	Unknown			Not Reported
Ineffective; Nausea; Neutropenia;	Hydroxychloroquine			S	Unknown			Not Reported

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Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845029	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609758			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845030	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609836			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pulmonary Fibrosis; Synovitis	Rituximab			S	Unknown	3.0 Years		Not Reported
	Enbrel			S	Unknown	260.0 Days		Not Reported
	Humira			S	Subcutaneous	346.0 Days		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine Sulfate	S	Unknown	9.0 Years	Not Reported
	Methotrexate	S	Unknown	2040.0 Days	Not Reported
	Remicade	S	Unknown	2.0 Years	Not Reported
	Prednisone	C	Unknown		Not Reported
	Xeljanz	C	Oral	2.0 Years	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845067	EXPEDITED (15-DAY)	HO		CA-ROCHE-2610757			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Nausea; Neutropenia; Off Label Use; Osteoarthritis; Synovitis; White Blood Cell Count Decreased	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845119	EXPEDITED (15-DAY)	OT		CA-ROCHE-2606900			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Fatigue; Glossodynia; Hand Deformity; Pain;	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

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Pemphigus; Swelling; Systemic Lupus Erythematosus; Wound	Cetirizine Hydrochloride	S	Unknown		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Folic Acid	S	Unknown		Not Reported
	Fosamax	S	Unknown		Not Reported
	Humira	S	Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Orencia	S	Intravenous (not otherwise specified)		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown		Not Reported
	Prednisone	S	Unknown		Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituxan	S	Intravenous (not otherwise specified)		Not Reported
	Simponi	S	Subcutaneous	Solution For Injection In Pre-Filled Pen	Not Reported
	Sulfasalazine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845121	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606664		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Colitis Microscopic; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Glaucoma; Synovitis; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Dorzolamide	C	Unknown	Not Reported
	Hydrochloride;Timolol Maleate	C	Unknown	Not Reported
	Ergocalciferol	C	Unknown	Not Reported
	Estradiol	C	Unknown	Not Reported
	Estrogel	C	Unknown	Not Reported
	Furosemide	C	Unknown	Not Reported
	Gravol	C	Unknown	Not Reported
	Potassium Chloride	C	Unknown	Not Reported
	Valsartan	C	Unknown	Not Reported
	Xalatan	C	Ophthalmic	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845122	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021834			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Drug-Induced Liver Injury; Headache	Cimzia			S	Subcutaneous	200 Milligram, Ev 2 Weeks(Qow)		Not Reported
	Azathioprine			S		150 Milligram, Once Daily (Qd)		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Orencia			S	Subcutaneous	125 Milligram, Weekly (Qw)		Not Reported
	Methotrexate			C	Subcutaneous	15 Milligram, Weekly (Qw)		Not Reported
	Sulfasalazine			C		500 Milligram, 2x/Day (Bid)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845152	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606067		80 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Off Label Use; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enbrel	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Allopurinol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845179	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1241649		79 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Erythema; Rash Pustular	Darunavir			S	Oral	800mg		Teva
	Ritonavir Sandoz			S	Oral	1 Dosage Form		Not Reported
	Plaquenil			S	Oral	2 Dosage Form		Not Reported
	Arixtra 2.5 Mg/0.5 MI Solution For Injection Pre-Filled Syringe			C	Subcutaneous	1 Dosage Form		Not Reported
	Clexane			C	Subcutaneous	1 Dosage Form		Not Reported
	Folina 5 Mg Capsule Molli			C				Not Reported
	Medrol 16 Mg Compresse			C				Not Reported
	Tazocin 4 G/0,5 G Polvere Per Soluzione Per Infusione			C	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported
	Kineret			C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported
	Dibase 10.000 U.I./MI Gocce Orali, Soluzione			C				Not Reported
	Azitromicina Teva 500 Mg Compresse Rivestite Con Film			C	Oral	1 Dosage Form		Not Reported
	Omeprazole Sodium			C				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845189	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609143		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Rituximab			S	Intravenous drip			Not Reported	
Diarrhoea; Drug	Etanercept			S	Subcutaneous			Not Reported	
Ineffective For	Humira			S	Subcutaneous			Not Reported	
Unapproved Indication;	Hydroxychloroquine			S	Subcutaneous			Not Reported	
Hypersensitivity; Incorrect	Methotrexate			S	Subcutaneous			Not Reported	
Route Of Product	Methotrexate			S	Oral			Not Reported	
Administration; Laryngeal	Varicella-Zoster Immune			S	Subcutaneous			Not Reported	
Disorder; Nausea;	Globulin								
Pruritus; Treatment	Varicella-Zoster Immune			S	Oral			Not Reported	
Failure; Weight Decreased	Globulin								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845263	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609821			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction;	Rituximab			S	Unknown			Not Reported	
Arthralgia; Drug	Abatacept			S	Unknown			Not Reported	
Ineffective; Joint Swelling	Adalimumab			S	Subcutaneous			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Gold			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Amitriptyline			C				Not Reported	
	Cefazolin			C				Not Reported	
	Clindamycin			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	C	Unknown	Not Reported
Tylenol With Codeine No.3	C		Not Reported
Xeljanz	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845264	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609745			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845290	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605381		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Ineffective; Joint Swelling; Musculoskeletal Disorder; Nasopharyngitis; Neutropenia; Off Label Use; Platelet Count Decreased; Rheumatoid Arthritis; Sinusitis; Skin Papilloma; Sleep Disorder;	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tendon Disorder; Thrombocytopenia	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S		Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Xeljanz	S	Oral	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845339	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609611		30 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Gait Inability; Movement Disorder; Nausea; Pain; Weight Increased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Cymbalta			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845432	EXPEDITED (15-DAY)		OT	CA-ROCHE-2611697			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Rheumatoid Arthritis; Rheumatoid Nodule; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Orencia			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Simponi	S	Subcutaneous	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606980			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845521	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-02514		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During	Hydroxychloroquine			S	Unknown	Unk		Lupin

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Premature Delivery	Prednisone	S	Unknown	Unk	Not Reported
	Insulin	S	Unknown	Unk	Not Reported
	Aspirine	S	Unknown	Unk	Not Reported
	Nifedipine	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Magnesium	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845639	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607143			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Drug Intolerance; Joint Swelling; Off Label Use; Product Use Issue; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown	Therapy Duration: 1460.0 Days		Not Reported
	Azathioprine			S	Oral			Not Reported
	Depo-Medrol With Lidocaine			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous	Therapy Duration: 187.0 Days		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous			Not Reported
	Ketoprofen			S	Topical			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Prevnar 13			S	Intramuscular	Therapy Duration: 1.0 Days		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845687	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242647		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
Piroxicam			C	Unknown			Not Reported	
Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845790	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606657			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra	S	Unknown	Not Reported
	Apo-Leflunomide	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	C	Unknown	Not Reported
	Meloxicam	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845826	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606204		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Condition Aggravated; Drug Ineffective; Impaired Work Ability; Nasopharyngitis; Rheumatoid Arthritis; Stress; Therapeutic Product Effect Decreased; Therapeutic Product Effect Incomplete	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Celebrex			S				Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Vioxx	S	Oral	Not Reported
Xeljanz	S	Oral	Not Reported
Sulfasalazine	C	Unknown	Not Reported
Wellbutrin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845829	EXPEDITED (15-DAY)		DS	CA-ROCHE-2606963		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Disability; Disease Recurrence; Drug Ineffective; Dyspnoea; Impaired Work Ability; Insomnia; Joint Lock; Joint Swelling; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Mass; Mobility Decreased; Musculoskeletal Stiffness; Off Label Use; Pain; Peripheral Swelling; Physical Disability; Rash; Rheumatoid Arthritis; Skin Mass; Sleep Disorder; Therapeutic Product Effect Decreased; Therapy Non-Responder	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Subcutaneous			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone Acetate	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Intramuscular	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Ergocalciferol	C		Not Reported
	Risedronate Sodium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845832	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606678		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Breast Cancer; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Hand Deformity; Headache; Infection; Intentional Product Use Issue; Joint Swelling; Loss Of Consciousness; Off Label Use; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate	S	Endocervical	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Sodium Aurothiomalate	S	Parenteral	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Meloxicam	C		Not Reported
	Simponi	C		Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845902	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US- 001724			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose	Hydroxychloroquine			S	Oral	Approximately 10-11 Gram		Ipca

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845914	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1241289		56 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxicloroquina			S		200 Mg		Teva
	Azitromicina			S		500 Mg		Not Reported
	Kaletra			S		1 Dosage Form		Not Reported
	Interferon Beta			S		250 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845932	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

INC.-2020-02532

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia Neonatal; Bronchopulmonary Dysplasia; Failure To Thrive; Fat Tissue Increased; Foetal Exposure During Pregnancy; Foetal Growth Restriction; Haemangioma; Infantile Apnoea; Postnatal Growth Restriction; Premature Baby; Pulmonary Hypertension; Retinopathy Of Prematurity	Hydroxychloroquine			S	Transplacental	Unk		Lupin
	Sildenafil			S	Unknown	1 Milligram/Kilogram, Tid		Lupin
	Prednisone			S	Transplacental	Unk		Not Reported
	Insulin			S	Transplacental	Unk		Not Reported
	Aspirine			S	Transplacental	Unk		Not Reported
	Nifedipine			S	Transplacental	Unk		Not Reported
	Magnesium			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845945	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608779			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Drug Intolerance; Gastric Disorder; Musculoskeletal Pain; Pain; Peripheral Swelling; Rash; Skin Ulcer	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17845972	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1241448		88 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminaemia	Hydroxychloroquine Sulfate			S	Oral	400 Mg		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846128	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1241996		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Teva	
	Mycophenolate Mofetil			S	Oral			Teva	
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S				Not Reported	
	Cymbalta			C	Unknown			Not Reported	
	Domperidone			C	Unknown			Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846163	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606404		77 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Drug Ineffective; Gait Disturbance; Nerve Compression	Actemra			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Therapy Duration: 5.0 Years		Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown	Therapy Duration: 8.0		Not Reported	

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Sulfasalazine			S		Unknown		Years		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846172	EXPEDITED (15-DAY)		DE, OT	ES-ACCORD-183691		86 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Off Label Use	Hydroxychloroquine			S				Not Reported	
	Kaletra			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846174	EXPEDITED (15-DAY)		OT	AU-ROCHE-2611142			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Graft Versus Host Disease In Skin	Mabthera			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Ibrutinib			S	Unknown			Not Reported	
	Prednisolone			S	Unknown			Not Reported	
	Sirolimus			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Lamotrigine			C	Unknown			Not Reported	
	Quetiapine			C				Not Reported	
	Bactrim Ds			C				Not Reported	
	Valaciclovir			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846261	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242759		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy;	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	

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Rash; Sinusitis	Actemra	S	Subcutaneous	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605494		56 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain; Alopecia; Arthropathy; Condition Aggravated; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Fatigue; Fibromyalgia; Glossodynia; Hand Deformity; Nausea; Oedema; Off Label Use; Pain; Pemphigus; Prescribed Overdose; Rheumatoid Arthritis; Synovitis; Systemic Lupus Erythematous; Vomiting	Actemra			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported

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Fosamax	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846344	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606618			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer Female; Condition Aggravated; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Vomiting	Actemra			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Meloxicam			C	Unknown			Not Reported
	Sulfasalazine			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846438	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241766		57 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Piperacilina Tazobactam			S	Intravenous (not otherwise specified)	1 Amp/8h		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846439	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241777		81 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatic Encephalopathy; Pancytopenia	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Amoxicilina Clavulanico			S	Intravenous (not otherwise specified)	1 Gr Every 12 Hours X 5 Days Followed By 1gr Every 8 Hours X 6 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846467	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606512		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Infection; Nausea; Nodule; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	

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Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Risedronate Sodium	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846492	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609048		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Inflammation; Musculoskeletal Stiffness; Rheumatoid Arthritis; Treatment Failure	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Gold			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846572	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020212010		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846584	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608772			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pain; Rheumatoid Arthritis; Therapeutic Product Effect Decreased; Therapeutic Response Decreased	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Myochrysine			S	Intramuscular			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846599	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605656		55 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthralgia; Asthenia; Blood Cholesterol Increased; Condition Aggravated; Disease Recurrence; Drug Ineffective; Drug Interaction; Drug Intolerance; Gastrooesophageal Reflux Disease; Impaired Work Ability; Malaise; Mobility Decreased; Movement Disorder; Muscle Spasms; Off Label Use; Pain; Pain In Jaw; Product Complaint; Rash; Swelling; Synovitis; Therapeutic Response Decreased; Wrist Deformity	Actemra			S	Unknown			Not Reported	
	Allopurinol			S	Unknown			Not Reported	
	Amitriptyline			S	Unknown			Not Reported	
	Amitriptyline			S	Unknown			Not Reported	
	Amitriptyline			S	Unknown			Not Reported	
	Hydrochloride;Perphenazine			S	Unknown			Not Reported	
	Apo-Amitriptyline			S	Unknown			Not Reported	
	Apo-Azathioprine			S	Unknown			Not Reported	
	Apo-Diclofenac			S	Topical			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Apo-Naproxen			S	Unknown			Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	

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Celebrex	S		Not Reported
Celecoxib	S	Unknown	Not Reported
Celecoxib	S		Not Reported
Diclofenac	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Diclofenac Sodium/Misoprostol	S	Unknown	Not Reported
Enbrel	S	Subcutaneous	Not Reported
Etanercept	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulphate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Misoprostol	S	Unknown	Not Reported
Naprosyn [Naproxen]	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Nifedipine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Rituximab	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Winpred	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported

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Diclofenac Sodium			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846771	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1241465		86 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S				Not Reported	
	Kaletra			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846790	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606913			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Fibrosis; Ill-Defined Disorder; Inflammation; Joint Swelling; Musculoskeletal Stiffness; Treatment Failure	Actemra			S	Unknown			Not Reported	
	Etanercept			S	Unknown	2190.0 Days		Not Reported	
	Humira			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846996	EXPEDITED (15-DAY)		OT	CA-ROCHE-2607028			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Product Use Issue; Rheumatoid	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous drip			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Diclofenac Sodium			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthritis; Systemic Lupus Erythematosus	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846998	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2020212284			Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemolytic Anaemia	Etanercept			S		Unk		Pfizer
	Sulfasalazine			S		Unk		Pfizer
	Methotrexate			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847019	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606601		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthralgia; Blood Cholesterol Increased; Contraindicated Product Administered; Drug	Actemra			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; General Physical Health	Cetirizine Hydrochloride	S	Unknown	Not Reported
Deterioration; Headache; Hypersensitivity;	Cimzia	S	Subcutaneous	Not Reported
Hypertension; Joint Swelling; Maternal Exposure During Pregnancy;	Cimzia	S	Unknown	Not Reported
Musculoskeletal Stiffness; Pain; Pemphigus;	Cortisone Acetate	S	Unknown	Not Reported
Pericarditis; Product Use Issue; Rheumatic Fever;	Desoximetasone	S	Oral	Not Reported
Rheumatoid Arthritis; Swelling; Swollen Joint Count Increased;	Diclofenac	S	Unknown	Not Reported
Synovitis; Systemic Lupus Erythematosus;	Enbrel	S	Subcutaneous	Not Reported
Therapeutic Product Effect Decreased; Treatment Failure; Type 2 Diabetes Mellitus	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hcl	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847045	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020211935		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Repolarisation Abnormality; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Rocephin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847047	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020212312		11 YR	Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Off Label Use; Product Use In Unapproved Indication; Shock	Azithromycin			S	Unknown	Unk		Pfizer	
	Methylprednisolone Sodium Succinate			S	Unknown	Unk		Pfizer	
	Lopinavir/Ritonavir			S	Oral	Unk		Not Reported	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847132	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020211145			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Meningitis; Pain; Rheumatoid Arthritis; Swelling; Therapeutic Product Effect Decreased	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Sulfasalazine			S	Unknown	Unk		Pfizer	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Remicade			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847143	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606599			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Off Label Use; Pneumonia	Actemra			S	Subcutaneous			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847178	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606680			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Arava			S	Oral			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847192	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606635		51 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Intolerance; Laboratory Test Abnormal; Neuropathy Peripheral; Prerenal Failure; Renal Disorder; Treatment Failure	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847247	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608755			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Pulmonary Fibrosis; Rheumatoid Arthritis; Synovitis	Rituximab	S	Unknown	Therapy Duration:3.0 Years	Not Reported
	Enbrel	S	Unknown	Therapy Duration: 9.0 Months	Not Reported
	Humira	S	Subcutaneous	Therapy Duration: 346.0 Days	Not Reported
	Hydroxychloroquine	S	Unknown	Therapy Duration: 9.0 Years	Not Reported
	Methotrexate	S	Unknown	Therapy Duration: 7.0 Years	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Therapy Duration: 2.0 Years	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847279	EXPEDITED (15-DAY)	CA		NVSC2020US148890			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Lymphopenia; Premature Baby	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Transplacental	Unk		Novartis	
	Tacrolimus			S	Transplacental	Unk		Not Reported	
	Prednisone			S	Transplacental	Unk		Not Reported	
	Betamethasone			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847317	EXPEDITED (15-DAY)	OT		CA-ROCHE-2607208		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Adverse Drug Reaction; Anti-Cyclic Citrullinated Peptide Antibody; Drug Ineffective; Intentional Product Use Issue; Joint Swelling; Leukopenia;	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Pain; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Toxicity To Various Agents; Visual Impairment	Leflunomide Orencia	S S	Unknown Unknown	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847581	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606548		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Drug Ineffective;	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
Drug Intolerance; Fatigue;	Arava			S	Unknown			Not Reported
Glossodynia; Hand	Cetirizine Hydrochloride			S	Unknown			Not Reported
Deformity; Hip	Cetirizine Hydrochloride			S	Unknown			Not Reported
Arthroplasty; Knee	Enbrel			S	Unknown			Not Reported
Arthroplasty; Maternal	Cimzia			S	Subcutaneous			Not Reported
Exposure During	Folic Acid			S	Unknown			Not Reported
Pregnancy; Off Label Use;	Fosamax			S	Unknown			Not Reported
Pain; Pemphigus;	Humira			S	Subcutaneous			Not Reported
Rheumatoid Arthritis;	Hydroxychloroquine Sulfate			S	Urethral			Not Reported
Swelling; Systemic Lupus	Methotrexate			S	Oral			Not Reported
Erythematosis	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Adalimumab			S	Subcutaneous			Not Reported
	Simponi			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Sulfasalazine		S	Oral				Not Reported	
	Xeljanz		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847583	EXPEDITED (15-DAY)		OT	US-009507513-2005USA008649			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Lymphocytopenia Neonatal	Celestone Soluspan			S		Unk		Merck	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	
	Azathioprine			S		Unk		Not Reported	
	Tacrolimus			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847587	EXPEDITED (15-DAY)		OT	CA-ROCHE-2608166			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angiopathy; Panniculitis	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Colchicine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847672	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606953		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Headache; Off Label Use; Product Use Issue; Rheumatoid Arthritis; Viral	Actemra			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection	Methotrexate	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847685	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606636		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; C-Reactive Protein Increased; Colitis Microscopic; Diverticulitis; Drug Ineffective; Drug Intolerance; Glaucoma; Off Label Use; Synovitis	Actemra			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Dorzolamide Hydrochloride;Timolol Maleate			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Estrogel			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Morphine			C				Not Reported
	Potassium Chloride			C	Unknown			Not Reported
	Valsartan			C	Unknown			Not Reported
	Xalatan			C	Unknown			Not Reported
	Zingiber Officinale			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847686	NON-EXPEDITED			US-009507513-2006USA000273			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Celestone Soluspan			S		Unk		Merck
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Tacrolimus			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847700	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2020-CA-1242689		27 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Mycophenolate Mofetil			S	Unknown			Teva
	Apo-Azathioprine			S	Unknown	100 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	50 Milligram Daily;		Not Reported
	Apo-Azathioprine			S	Unknown	20 Milligram Daily;		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Procytox			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847704	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242753		71 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
Piroxicam			C					Not Reported	
Prednisone			C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847787	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-042381			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Headache; Rheumatoid Arthritis; Tremor	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
Remicade	S	Intravenous (not otherwise specified)		Not Reported
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Simponi	S	Subcutaneous		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Folic Acid	C	Unknown		Not Reported
Pantoprazole Magnesium	C	Unknown		Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown		Not Reported
Xeljanz	C	Unknown		Not Reported
Zopiclone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17847848	EXPEDITED (15-DAY)		OT	CA-ROCHE-2540932		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Arthropathy; Contraindicated Product Administered; Drug Ineffective; Finger Deformity; Gait Disturbance; Therapeutic Product Effect Decreased	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S		Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17848194	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-3205448-00		32 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diabetes Mellitus; Drug Ineffective; Drug Intolerance; Fibromyalgia; Lymphoedema; Obesity; Pneumocystis Jirovecii Pneumonia; Pulmonary Embolism	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Xarelto			C				Not Reported
	Prednisone			C		Qd, Tapering		Not Reported
	Hydrocortisone			C				Not Reported
	Tylenol Arthritis			C				Not Reported
	Calcium Vitamin D			C				Not Reported
	Pantoloc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	8644662	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY-16703324		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Abnormal; Back Pain; Blood Pressure Abnormal;	Abatacept			S	Unknown	Inf:8,Last Infusion On 24-May-2012 Last Infusion On 15-Jan-2014. 3j75953-		Bristol Myers Squibb



Detailed Report

Exp Date:Jul-2016.

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metformin	C	Unknown	5 Milligram, Qd	Not Reported
Lorazepam	C	Unknown	1 Milligram, Qd	Not Reported
Vagifem	C	Unknown	Unk	Not Reported
Premarin	C	Unknown	0.625 Milligram	Not Reported
Vitamin D [Ergocalciferol]	C	Unknown		Not Reported
Calcium	C	Unknown		Not Reported
Tylenol Arthritis	C	Unknown	Unk, Q8h	Not Reported
Actonel	C	Unknown	35 Milligram, Qwk	Not Reported
Methylprednisolone Acetate	C	Unknown		Not Reported
Methylprednisolone Acetate	C	Subcutaneous	Unk, Qmo	Not Reported
Methylprednisolone Acetate	C	Subcutaneous	40 Milligram, Qmo	Not Reported
Methylprednisolone Acetate	C	Intramuscular	40 Milligram, Qmo	Not Reported
Ergocalciferol	C	Unknown		Not Reported
Nortriptylin	C	Unknown	20 Milligram, Qd	Not Reported
Nortriptylin	C	Unknown		Not Reported
Risedronate Sodium	C	Unknown	35 Milligram, Qwk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	12308608	EXPEDITED (15-DAY)		DS, OT	CA-ROCHE-1745459		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Anti-Cyclic	Rituxan			S	Intravenous (not			Not Reported
Citrullinated Peptide					otherwise specified)			
Antibody Positive;	Rituxan			S	Intravenous (not	Therapy Duration: 365.0		Not Reported
Arthropathy; Condition					otherwise specified)	Nos		
Aggravated;	Rituxan			S	Intravenous (not			Not Reported
Contraindicated Product					otherwise specified)			
Administered; Discomfort;	Arava			S	Oral			Not Reported
Drug Ineffective; Drug	Arava			S	Unknown			Not Reported
Intolerance; Duodenal								
Ulcer Perforation; Fatigue;								
Glossodynia; Glossodynia;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hand Deformity;	Cimzia	S	Subcutaneous	Not Reported
Helicobacter Infection;	Cimzia	S	Unknown	Not Reported
Hepatic Enzyme	Enbrel	S	Subcutaneous	Not Reported
Increased; Hip	Enbrel	S	Unknown	Not Reported
Arthroplasty; Infusion	Enbrel	S	Unknown	Not Reported
Related Reaction; Joint	Enbrel	S	Unknown	Not Reported
Swelling; Knee	Enbrel	S	Subcutaneous	Not Reported
Arthroplasty; Maternal	Enbrel	S	Unknown	Not Reported
Exposure During	Enbrel	S	Subcutaneous	Not Reported
Pregnancy; Off Label Use;	Enbrel	S	Unknown	Not Reported
Pain; Pemphigus; Product	Enbrel	S	Subcutaneous	Not Reported
Use Issue; Rash;	Folic Acid	S	Unknown	Not Reported
Rheumatoid Arthritis;	Folic Acid	S	Unknown	Not Reported
Rheumatoid Factor	Folic Acid	S	Unknown	Not Reported
Positive; Swelling;	Folic Acid	S	Oral	Not Reported
Synovitis; Systemic Lupus	Folic Acid	S	Unknown	Not Reported
Erythematous; Treatment	Folic Acid	S	Unknown	Not Reported
Failure; Wound	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Orencia	S	Subcutaneous	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Intravenous (not otherwise specified)	Not Reported
Prednisone	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Remicade	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Simponi	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Unknown	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Cutaneous	Not Reported
Desoximetasone	S	Oral	Not Reported
Desoximetasone	S	Unknown	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Cortisone	S	Oral	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Unknown	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Cortisone Acetate	S	Unknown	Not Reported
Diclofenac Sodium	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Sarilumab	S	Unknown	Not Reported
Stelara	S	Unknown	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Duration- 365 Not Reported
Alendronate Sodium	S	Oral	Not Reported
Alendronate Sodium	S	Unknown	Not Reported
Alendronate Sodium	S	Oral	Not Reported
Cortisone	S	Oral	Not Reported
Cortisone	S	Oral	Not Reported
Cortisone	S	Oral	Not Reported
Acetaminophen	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported
Apo Hydroxyquine	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Folic Acid	S	Unknown	Not Reported
Hydroxychloroquine Phosphate	S	Oral	Not Reported
Methotrexate Sodium	S	Oral	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Etanercept	S	Subcutaneous	Not Reported
Atasol [Caffeine Citrate;Codeine Phosphate;Paracetamol]	C		Not Reported
Zyrtec-D	C		Not Reported
Salazopyrin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	12769954	EXPEDITED (15-DAY)		DS, HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-076679			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Arthralgia; Coeliac Disease; Drug Ineffective; Fatigue; Grip Strength Decreased; Headache; Injection Site Reaction; Joint Swelling; Loss Of Personal Independence In Daily Activities; Movement Disorder; Musculoskeletal Stiffness; Nail Disorder; Onychomadesis; Onychomycosis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	500 Milligram		Not Reported
	Xeljanz			S	Unknown	5 Milligram, Bid		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Apo-Hydroxyquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Unk	Not Reported
Rituxan	S	Subcutaneous	Unk	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S	Oral	Unk	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Arava	C	Oral	Unk	Not Reported
Hydroxychloroquine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	12912801	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091708		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Arthropathy; Bone Disorder; C-Reactive Protein Abnormal; Drug Eruption; Drug Ineffective; Fall; Fatigue; Femur Fracture; Fracture Delayed Union; Impaired Healing; Joint Laxity; Limb Deformity; Loose Body In Joint; Malaise; Multiple Fractures; Osteoporosis; Osteoporotic Fracture; Pain; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown	Unk		Not Reported
	Adalimumab			S	Subcutaneous	Unk		Not Reported
	Apo-Leflunomide			S	Oral	5 Milligram, Q12h		Not Reported
	Apo-Naproxen			S	Unknown	Unk		Not Reported
	Apo-Prednisone			S	Unknown	Unk		Not Reported
	Cosentyx			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Unknown	20 Milligram		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Naproxen Sodium			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine Sulfate	S	Endocervical	400 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone Acetate	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Tocilizumab	S	Unknown	Unk	Not Reported
Folic Acid	C	Subcutaneous	Unk	Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Unk	Not Reported
Insulin	C	Oral	Drops Oral	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Acetaminophen And Codeine	C	Unknown		Not Reported
Celebrex	C	Unknown	2 Dosage Form, Qd	Not Reported
Metformin	C	Unknown	1 Dosage Form	Not Reported
Metformin	C	Unknown	2 Dosage Form, Bid	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C	Unknown	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unknown	Unk	Not Reported
Methotrexate	C	Unknown	20 Milligram	Not Reported
Leflunomide	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	12913692	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091875		79 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; C-Reactive Protein Increased; Drug Ineffective; Drug Intolerance; Dyspnoea; Fatigue; Helicobacter Infection; Hot Flush; Hypertension; Joint Swelling; Synovitis; Therapeutic Response Decreased	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Intracardiac	8 Milligram/Kilogram		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Milligram		Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Unk	Not Reported
Leflunomide	S	Oral	Unk	Not Reported
Methotrexate	S	Unknown	Unk	Not Reported
Methotrexate Sodium	S	Unknown	Unk	Not Reported
Rituximab;Vorhyaluronidase Alfa	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Hydroxychloroquine Sulphate	S	Oral	Unk	Not Reported
Apo-Leflunomide	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	40 Milligram	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	1000 Milligram	Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	C	Unknown	Unk	Not Reported
Premarin	C	Unknown	Unk	Not Reported
Tenormin	C	Unknown	Unk	Not Reported
Xeljanz	C	Unknown	Unk	Not Reported
Cymbalta	C	Unknown	Unk	Not Reported
Arava	C	Unknown	Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk	Not Reported
Elavil [Amitriptyline Hydrochloride]	C	Unknown	Unk	Not Reported
Imitrex [Sumatriptan]	C	Unknown	Unk	Not Reported
Lyrica	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	Unk	Not Reported
Acetaminophen	C	Unknown	Unk	Not Reported
Sumatriptan Succinate	C	Unknown	Unk	Not Reported
Amitriptyline Hydrochloride	C	Unknown	Unk	Not Reported
Amitriptyline	C	Unknown		Not Reported
Sumatriptan	C	Unknown		Not Reported
Tofacitinib	C	Unknown		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	13058525	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015728		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Apo-Leflunomide			S	Oral	20 Mg, Qd		Apotex
	Apo-Azathioprine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Apotex
	Anakinra			S	Subcutaneous	Unk		Not Reported
	Anakinra			S	Unknown	100 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	25 Mg, Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk Unk, Q.Wk.		Not Reported
	Gold			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	100 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Kineret			S	Unknown	100 Mg, Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	13286858	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1899556		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>



Detailed Report

[illegible]

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omega 3 Fish Oils	S	Unknown	Not Reported
Orencia	S	Vaginal	Not Reported
Orencia	S		Not Reported
Xeljanz	S	Oral	Not Reported
Thiamine Hydrochloride	S	Unknown	Not Reported
Thiamine Hydrochloride	S	Unknown	Not Reported
Vitamin B-1	S	Unknown	Not Reported
Xeljanz	S	Endocervical	Not Reported
Acetaminophen;Oxycodone Hydrochloride	C	Unknown	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Not Reported
Aclasta	C	Intravenous (not otherwise specified)	Not Reported
Actonel	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Ferrous Gluconate	C	Unknown	Not Reported
Loperamide Hydrochloride	C	Unknown	Not Reported
Nasonex	C	Unknown	Not Reported
Pantoprazole Magnesium	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Trazodone Hydrochloride	C	Oral	Not Reported
Tylenol	C	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetaminophen	C	Unknown	Not Reported
Apo-Gabapentin	C	Oral	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	C	Unknown	Not Reported
Biotin	C	Unknown	Not Reported
Cholecalciferol	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
D-Alpha Tocopheryl Acetate	C	Unknown	Not Reported
Diphenoxylate	C	Unknown	Not Reported
Diphenoxylate	C	Unknown	Not Reported
Docosahexaenoic Acid	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Esomeprazole Magnesium Trihydrate	C	Unknown	Not Reported
Fergon	C	Unknown	Not Reported
Ferrous Fumarate	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	C	Unknown	Not Reported
Loperamide	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported
Nicotinamide	C	Unknown	Not Reported
Perphenazine	C	Oral	Not Reported
Perphenazine	C	Unknown	Not Reported
Pyridoxine	C	Unknown	Not Reported
Pyridoxine Hydrochloride	C	Unknown	Not Reported
Retinol Palmitate	C	Unknown	Not Reported
Riboflavin	C	Unknown	Not Reported
Sodium Ascorbate	C	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Tecta	C	Unknown	Not Reported
	Thiamine Hydrochloride	C	Unknown	Not Reported
	Thiamine Mononitrate	C	Unknown	Not Reported
	Trazodone	C	Unknown	Not Reported
	Vitamin B12 [Cyanocobalamin]	C		Not Reported
	Vitamin D3	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	13984193	EXPEDITED (15-DAY)		OT	CA-ROCHE-1993146			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breast Cancer; Condition Aggravated; Drug Ineffective; Infection; Loss Of Consciousness; Off Label Use; Rheumatoid Arthritis; Synovitis; Treatment Failure; Vomiting	Actemra			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown	Therapy Duration: 730 Nos		Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown	Therapy Duration: 4 Years		Not Reported
	Meloxicam			C				Not Reported
	Sulfasalazine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	13988289	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-083265		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Orencia			S	Unknown	40 Milligram, Q2wk		Bristol Myers Squibb	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Headache; Off Label Use; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Tremor	Actemra	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Milligram, Qwk	Not Reported
	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	300 Milligram	Not Reported
	Remicade	S	Unknown	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	200 Milligram, Bid	Not Reported
	Methotrexate	S	Oral	2.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Oral	10 Milligram, Qwk	Not Reported
	Adalimumab	S	Unknown	Unk	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	Unk	Not Reported
	Cimzia	S	Unknown	Unk	Not Reported
	Methotrexate	C	Oral	10.0 Milligram, Qwk	Not Reported
	Methotrexate	C	Oral	15.0 Milligram, Qwk	Not Reported
	Methotrexate	C	Oral	2.5 Milligram, Qwk	Not Reported
	Methotrexate	C	Unknown	1 Dosage Form, Qwk	Not Reported
	Folic Acid	C	Oral	2.5 Milligram, Qd	Not Reported
	Pantoprazole	C	Oral	40 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported
	Zopiclone	C	Unknown	7.5 Milligram, Qd	Not Reported
	Tenofovir Disoproxil Fumarate	C	Oral	300 Milligram	Not Reported
	Pantoprazole Sodium Sesquihydrate	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tenofovir Disoproxil	C	Unknown	Unk	Not Reported
Tenofovir	C	Unknown	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Tenofovir Disoproxil Fumarate	C	Unknown	300 Milligram	Not Reported
Pantoprazole Sodium Anhydrous	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	14206623	EXPEDITED (15-DAY)		OT	CA-ROCHE-2025500		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Drug Ineffective; Osteoarthritis; Rheumatoid Factor Positive; Synovitis	Rituximab			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			C	Subcutaneous			Not Reported
	Xeljanz			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	14917666	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007162		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Intolerance; Extremity Contracture; Nausea; Psoriasis; Pustular Psoriasis; Rheumatoid	Orencia			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthritis; Scar; Vomiting	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Mg, Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Leflunomide	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]	S	Unknown		Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Unk	Not Reported
	Tofacitinib Citrate	S	Oral	5.0 Mg, Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	C	Unknown	Unk	Not Reported
	Cymbalta	C	Unknown	Unk	Not Reported
	Remicade	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydromorphone	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	14923972	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-044325			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bronchitis; Bronchospasm; Diarrhoea; Drug Intolerance; Lung Disorder; Muscle Spasms; Pneumonitis; Pyelonephritis; Rheumatoid Factor Negative; Synovitis	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Lyrica			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	25 Mg, Unk	Not Reported
Mirtazapine	S	Unknown	15 Mg, Unk	Not Reported
Sulfasalazine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	15422962	EXPEDITED (15-DAY)		OT	DE-ROCHE-2186283		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fatigue; Off Label Use; Treatment Failure	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous drip			Not Reported
	Rituximab			S	Oral			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous	20 Mg		Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Methotrexate Sodium			S	Oral			Not Reported
	Apo-Hydroxyquine			S	Subcutaneous	Unk		Not Reported
	Apo-Hydroxyquine			S	Oral	Unk		Not Reported
	Ciclosporin			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported
	Hydroxychloroquine			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Hydroxychloroquine	S	Oral		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Orencia	S	Subcutaneous		Not Reported
	Apo-Leflunomide	S	Unknown	Unk	Not Reported
	Apo-Leflunomide	S	Oral	Unk	Not Reported
	Neoral	S	Oral	Unk	Not Reported
	Neoral	S	Subcutaneous	Unk	Not Reported
	Leflunomide	S	Unknown		Not Reported
	Sulfasalazine	S	Oral		Not Reported
	Enbrel	S	Subcutaneous		Not Reported
	Xeljanz	C	Oral	5 Mg Bid	Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	15619727	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2555831-00		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Joint Swelling; Leukopenia; Rash; Rheumatoid Arthritis; Toxicity To Various Agents; Visual Impairment	Humira			S	Subcutaneous			Not Reported
	Actemra			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Xeljanz			C	Oral			Not Reported

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Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	15629381	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2558926-00		41 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fatigue; Hepatic Enzyme Abnormal; Liver Function Test Abnormal; Nodule; Rheumatoid Arthritis	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Apo-Leflunomide			S	Unknown			Not Reported	
	Methotrexate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	15801087	EXPEDITED (15-DAY)		HO, OT	CA-ABBVIE-19K-028-2617003-00		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Humira			S	Subcutaneous			Not Reported	
	Actemra			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Unknown			Not Reported	
	Apo-Leflunomide			S	Oral			Not Reported	
	Apo-Leflunomide			S				Not Reported	
	Apo-Prednisone			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Folic Acid			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Methotrexate Sodium	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Leucovorin	S	Unknown		Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Prednisone	S	Unknown	2 Dosage Forms	Not Reported
	Cimzia Single-Use Pre-Filled Syringe	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	15978220	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-013626			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Nausea; Oral Discomfort; Uveitis	Orencia			S	Unknown	Unk		Bristol Myers Squibb
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported
	Humira			S	Subcutaneous	40 Milligram, Qwk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Oral	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Simponi			S	Subcutaneous	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Tocilizumab			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	Unk		Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Subcutaneous	40 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	Intravenous (not otherwise specified)	Unk	Not Reported
Prednisone	C	Unknown	10 Milligram	Not Reported
Cimzia	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	16537770	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-063625		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cutaneous Vasculitis; Drug Ineffective; Drug Intolerance; Oral Mucosal Exfoliation; Osteoarthritis; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Secretion Discharge; Spinal Stenosis; Synovitis	Orencia			S	Intravenous (not otherwise specified)	500 Milligram, Qmo		Bristol Myers Squibb	
	Anakinra			S	Subcutaneous	100.0 Milligram, Qd		Not Reported	
	Apo-Leflunomide			S	Unknown	20.0 Milligram, Qd		Not Reported	
	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Milligram		Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Millilitre Per Kilogram		Not Reported	
	Methotrexate			S	Subcutaneous	12.5 Milligram		Not Reported	
	Methotrexate			S	Oral	20 Milligram, Qd		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram		Not Reported	
	Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported	
	Xeljanz			C	Unknown	5 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	16884373	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA- 201909000458			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Arthralgia; Drug Ineffective;	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Alemtuzumab			S	Intravenous drip	12 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspepsia; Frustration	Tysabri	C	Not Reported
Tolerance Decreased;	Copaxone	C	Not Reported
Hypersensitivity;	Betaseron	C	Not Reported
Increased Tendency To			
Bruise; Joint Stiffness;			
Paraesthesia Oral; Rash			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17157342	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019053627			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Cimzia			S	Subcutaneous	Unk		Ucb
Alopecia; Arthropathy;	Certolizumab Pegol			S	Subcutaneous	Unk		Ucb
Contraindicated Product	Cetirizine Hydrochloride			S		Unk		Not Reported
Administered; Drug	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Ineffective; Fatigue;	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
Glossodynia; Hand	Simponi			S	Subcutaneous	Solution		Not Reported
Deformity; Liver Injury;	Actemra			S	Intravenous (not otherwise specified)			Not Reported
Maternal Exposure During	Arava			S		Unk		Not Reported
Pregnancy; Off Label Use;	Arava			S	Unknown			Not Reported
Pain; Pemphigus; Product	Diclofenac Sodium			S				Not Reported
Use Issue; Psoriatic	Diclofenac Sodium			S		Unk		Not Reported
Arthropathy; Rheumatoid	Enbrel			S	Subcutaneous			Not Reported
Arthritis; Swelling;	Fosamax			S		Unk		Not Reported
Systemic Lupus	Fosamax			S	Unknown			Not Reported
Erythematous; Wound	Folic Acid			S				Not Reported
	Folic Acid			S		1 Milligram		Not Reported
	Humira			S	Subcutaneous	Solution		Ucb
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S		Solution	Not Reported
Methotrexate	S		Unk	Not Reported
Methotrexate	S		Unk	Not Reported
Orencia	S	Intravenous (not otherwise specified)		Not Reported
Orencia	S	Intravenous (not otherwise specified)	Unk	Not Reported
Orencia	S	Subcutaneous	Unk	Not Reported
Phthalylsulfathiazole	S			Not Reported
Phthalylsulfathiazole	S	Unknown		Not Reported
Plaquenil [Hydroxychloroquine Phosphate]	S			Not Reported
Prednisone	S		Unk	Not Reported
Prednisone	S			Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Solution	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown		Not Reported
Etanercept	S	Subcutaneous		Not Reported
Etanercept	S	Unknown	Unk	Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Plaquenil	S	Unknown		Not Reported
Desoximetasone	S	Oral		Not Reported
Sulfasalazine	S	Unknown		Not Reported
Cosentyx	S	Unknown		Not Reported
Calcium /00060701/	C	Unknown		Not Reported
Pantoprazole	C	Unknown		Not Reported
Quetiapine	C	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ramipril			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17281615	EXPEDITED (15-DAY)		OT	CA-ROCHE-2518250		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Blood Pressure Fluctuation; Blood Pressure Increased; Depression; Drug Ineffective; Drug Intolerance; Endodontic Procedure; Flushing; Heart Rate Decreased; Herpes Zoster; Ill-Defined Disorder; Impaired Healing; Infusion Related Reaction; Joint Swelling; Localised Infection; Malaise; Medication Error; Nasopharyngitis; Pain; Peripheral Swelling; Rash; Rheumatoid Arthritis; Skin Fissures; Smear Cervix Abnormal; Suicidal Ideation; Therapeutic Product Effect Decreased; Therapeutic Response Decreased; Therapy Non-Responder; Tooth Disorder; Toothache; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Anakinra			S	Unknown			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Infliximab			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Naproxen	S	Unknown		Not Reported
Kineret	S	Subcutaneous	Solution Subcutaneous, 100mg Per Syringe Single- Use, Preservative-Free Prefilled Syringes	Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Acetaminophen	C			Not Reported
Diphenhydramine Hydrochloride	C	Unknown		Not Reported
Ferrous Gluconate	C	Unknown		Not Reported
Folic Acid	C			Not Reported
Lasix [Furosemide]	C			Not Reported
Methylprednisolone	C			Not Reported
Naprosyn E	C			Not Reported
Oxycontin	C	Unknown	Tablet (Extended Release)	Not Reported
Oxyneo	C	Unknown	Tablet (Extended Release)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17351116	EXPEDITED (15-DAY)	OT		CA-ROCHE-2530650		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Erosion; Burning	Actemra			S	Unknown			Not Reported
Sensation; C-Reactive	Mycophenolate Mofetil			S	Unknown			Not Reported
Protein Abnormal; Chronic	Rituximab			S	Unknown			Not Reported
Kidney Disease;	Tocilizumab			S	Unknown			Not Reported
Contraindicated Product	Azathioprine			S	Unknown			Not Reported
Administered;	Ciprofloxacin			S	Unknown			Not Reported
Diverticulitis; Drug	Amoxicillin;Clavulanate			S	Unknown			Not Reported
Hypersensitivity; Drug	Potassium							
Ineffective; Drug	Enbrel			S	Unknown			Not Reported
Intolerance; Interstitial	Humira			S	Subcutaneous			Not Reported
Lung Disease; Joint	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Stiffness; Musculoskeletal	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Stiffness; Off Label Use;								
Sepsis; Synovitis;								
Systemic Lupus								
Erythematousus; Treatment								
Failure								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Unknown	Not Reported
Orencia	S	Unknown	Not Reported
Remicade	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
Amoxicillin Trihydrate; Clavulanate Potassium	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Amoxicillin Sodium; Clavulanate Potassium	S	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Tridural	C	Unknown	Not Reported
Tylenol	C	Unknown	Not Reported
Cimetidine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17363386	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-005934		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Loss Of Personal Independence In Daily Activities; Pneumonia; Pulmonary Fibrosis; Rheumatoid Arthritis	Orencia			S	Unknown	Unk		Bristol Myers Squibb	
	Actemra			S	Unknown	Unk		Not Reported	
	Apo-Leflunomide			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			C	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	C	otherwise specified)			
Prednisone	C	Unknown	5 Milligram, Qd		Not Reported
Prednisone	C	Unknown	10 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17364200	EXPEDITED (15-DAY)		OT	CA-ROCHE-2533943		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Chlorhexidine			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single Use		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Oxycodone Terephthalate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown			Not Reported
	Periogard			S	Unknown			Not Reported
	Act Oxycodone Cr			S	Unknown			Not Reported
	Sulfamethoxazole			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chlorhexidine Gluconate	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Acetaminophen; Oxycodone Hydrochloride	S	Unknown	Not Reported
Arava	C	Oral	Not Reported
Desogestrel; Ethinylestradiol	C		Not Reported
Ibuprofen	C		Not Reported
Pantoloc [Pantoprazole]	C		Not Reported
Pantoprazole Sodium	C		Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	C		Not Reported
Prednisone	C	Oral	Not Reported
Reactine [Cetirizine Hydrochloride]	C		Not Reported
Tylenol	C		Not Reported
Hydroxychloroquine Sulfate	C		Not Reported
Cetirizine Hydrochloride	C		Not Reported
Pantoprazole	C		Not Reported
Paracetamol	C		Not Reported
Cetirizine	C	Unknown	Not Reported
Hydroxychloroquine Phosphate	C	Unknown	Not Reported
Paracetamol Codeine	C	Unknown	Not Reported
Tylenol With Codeine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17399035	EXPEDITED (15-DAY)		HO, LT, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-010345		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Arthropathy; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Hypersensitivity; Drug Ineffective; Drug	Orencia			S	Intravenous (not otherwise specified)			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Anakinra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Feeling	Enbrel	S	Subcutaneous		Not Reported
Abnormal; Haemoglobin	Gold	S	Subcutaneous		Not Reported
Decreased; Herpes	Hydroxychloroquine Sulfate	S	Unknown	400 Milligram	Not Reported
Zoster; Interstitial Lung	Humira	S	Subcutaneous		Not Reported
Disease; Joint Swelling;	Methotrexate	S	Unknown		Not Reported
Myocardial Infarction; Off	Methotrexate	S	Unknown		Not Reported
Label Use; Pain;	Remicade	S	Intravenous (not		Not Reported
Photosensitivity Reaction;			otherwise specified)		
Pulmonary Embolism;	Rituximab	S	Intravenous (not		Not Reported
Pulmonary Thrombosis;			otherwise specified)		
Red Blood Cell					
Sedimentation Rate	Cannabis Sativa	S	Unknown		Not Reported
Increased; Renal Failure;	Sodium Aurothiomalate	S	Unknown		Not Reported
Sepsis; Stomatitis;	Minocycline Hydrochloride	S	Unknown		Not Reported
Terminal State;	Oxycodone	S	Unknown	10 Milligram	Not Reported
Thrombosis; Urticaria	Sulfasalazine	S	Unknown	500 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown		Not Reported
	Ilaris	C	Subcutaneous		Not Reported
	Plaquenil [Hydroxychloroquine	C	Unknown		Not Reported
	Sulfate]				
	Rituximab	C	Unknown		Not Reported
	Lyrica	C	Oral		Not Reported
	Xeljanz	C	Oral	Unk, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17424444	EXPEDITED (15-DAY)		OT	CA-ROCHE-2543750			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction;	Actemra			S	Unknown			Not Reported	
Arthritis; Bone Erosion;	Arava			S	Unknown			Not Reported	
Contraindicated Product	Azathioprine			S	Unknown			Not Reported	
Administered; Dizziness;	Cimzia			S	Subcutaneous			Not Reported	
Drug Hypersensitivity;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Drug-Induced Liver Injury; Exostosis; Foot Deformity; Headache; Hepatic Cirrhosis; Infection; Joint Dislocation; Joint Stiffness; Nausea; Off Label Use; Osteoarthritis; Osteoporosis; Pneumonia; Synovitis	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Minocycline	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sirukumab	S	Unknown	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Minocycline Hydrochloride	S	Unknown	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous drip	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Morphine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Cosentyx	S	Unknown	Not Reported
	Leflunomide	S	Oral	Not Reported
	Dilaudid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17486761	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202002001091			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acantholysis; Blister; Dermatitis; Herpes Zoster; Inflammation; Macule; Pain; Pruritus; Skin Plaque; Varicella Zoster Virus Infection	Hydroxychloroquine			S	Oral	100 Mg, Qd, Plaquenil Tablet		Concordia
	Prednisone			S	Unknown	40 Mg, Qd		Not Reported
	Prednisone			S	Unknown	35 Mg, Qd		Not Reported
	Prednisone			S	Unknown	30 Mg, Qd		Not Reported
	Prednisone			S	Unknown	25 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd, Tapering Dose		Not Reported
	Imuran			S	Oral	50 Mg, Qd		Not Reported
	Shingrix			S	Unknown	Unk,To Her Right Deltoid		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Ortho-Novum			C		Unk		Not Reported
	Zyrtec			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17552428	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-021329		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Hepatic Enzyme Increased; Pneumonia	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	40 Milligram		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Apo-Leflunomide			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone C Unknown 5 Milligram, Qd Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17563694	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-022541			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Orencia			S	Unknown			Bristol Myers Squibb
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17687059	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-032291		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy;	Orencia			S	Subcutaneous	Unk		Bristol Myers Squibb

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Musculoskeletal Discomfort; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosus	Orencia	S	Intravenous (not otherwise specified)		Bristol Myers Squibb
	Actemra	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Desoximetasone	S	Oral	Unk	Not Reported
	Enbrel	S	Subcutaneous	Unk	Not Reported
	Folic Acid	S	Unknown	Unk	Not Reported
	Fosamax	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulphate	S	Unknown	400 Milligram, Qd	Not Reported
	Methotrexate	S	Oral	25 Milligram	Not Reported
	Phthalylsulfathiazole	S	Unknown	Unk	Not Reported
	Prednisolone	S	Unknown	Unk	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	1 Gram, Bid	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17741749	EXPEDITED (15-DAY)		OT	CH-SA-2020SA114056			Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Plaquenil			S	Oral	In Total		Sanofi
	Amoxicillin Sodium/Potassium Clavulanate			S	Intravenous drip	1.2 G, Qid		Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lopinavir/Ritonavir	S	Oral	400 Mg, Bid	Not Reported
Clexane	S	Subcutaneous	40 Mg, Qd	Sanofi
Clexane	S	Subcutaneous	40 Mg, Bid	Sanofi
Clexane	S	Subcutaneous	Unk	Sanofi
Clexane	S	Subcutaneous	40 Mg, Bid	Sanofi
Paracetamol	S	Intravenous (not otherwise specified)	Max 3x/D ; As Necessary	Not Reported
Piperacillin/Tazobactam	S	Intravenous drip	4.5 G, Tid	Not Reported
Azithromycin	S	Oral	500 Mg, Qd	Not Reported
Ipramol	C		Unk	Not Reported
Temesta [Lorazepam]	C			Not Reported
Tavanic	C			Not Reported
Atracurium	C		Unk	Not Reported
Fentanyl	C		Unk	Not Reported
Dormicum [Midazolam Hydrochloride]	C		Unk	Not Reported
Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C		Unk	Not Reported
Antibiotics For Otic And Nasal Use	C		Unk	Not Reported
Torsemide	C			Not Reported
Potassium	C			Not Reported
Benerva	C			Not Reported
Heparin	C		Unk	Not Reported
Solu-Medrol	C		Unk	Not Reported
Novorapid	C		Unk	Not Reported
Relistor	C		Unk	Not Reported
Novasource Gi Control	C		Unk	Not Reported
Ventolin [Salbutamol]	C		Unk, Prn	Not Reported
Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C		Unk, Prn	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17765937	EXPEDITED (15-DAY)		OT	CA-ROCHE-1748865		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; C-Reactive Protein Abnormal; Contraindicated Product Administered; Drug Ineffective; Drug Intolerance; Fall; Fatigue; Femur Fracture; Hepatic Enzyme Increased; Infection; Knee Arthroplasty; Loss Of Personal Independence In Daily Activities; Loss Of Personal Independence In Daily Activities; Mobility Decreased; Mucosal Inflammation; Off Label Use; Osteoporosis; Pain; Rash; Synovitis	Actemra			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Naproxen Sodium			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Apo-Leflunomide			S	Unknown			Not Reported
	Apo-Naproxen			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Oral			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Prednisone			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported
	Risedronate			C	Oral			Not Reported
	Folic Acid			C				Not Reported
	Naproxen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17787135	EXPEDITED (15-DAY)		OT	CA-ROCHE-2593552		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaphylactic Reaction;	Actemra	S	Unknown	Not Reported
Arthralgia; Asthenia; Blood	Rituximab	S	Intravenous (not	Not Reported
Cholesterol Increased;			otherwise specified)	
Condition Aggravated;	Allopurinol	S	Unknown	Not Reported
Contraindicated Product	Amitriptyline	S	Unknown	Not Reported
Administered; Disease	Amitriptyline	S	Unknown	Not Reported
Recurrence; Drug	Amitriptyline	S	Unknown	Not Reported
Ineffective; Drug	Apo-Amitriptyline	S	Unknown	Not Reported
Interaction; Drug	Amitriptyline	S	Unknown	Not Reported
Intolerance;	Hydrochloride;Perphenazine	S	Unknown	Not Reported
Gastrooesophageal Reflux	Amitriptyline	S	Unknown	Not Reported
Disease; Impaired Work	Hydrochloride;Perphenazine	S	Unknown	Not Reported
Ability; Malaise; Mobility	Apo-Azathioprine	S	Unknown	Not Reported
Decreased; Movement	Apo-Diclo	S	Unknown	Not Reported
Disorder; Muscle Spasms;	Apo-Diclofenac	S	Topical	Not Reported
Off Label Use; Pain; Pain	Apo-Leflunomide	S	Unknown	Not Reported
In Jaw; Product	Apo-Naproxen	S	Unknown	Not Reported
Complaint; Rash;	Apo-Prednisone	S	Unknown	Not Reported
Rheumatoid Arthritis;	Apo-Prednisone	S	Unknown	Not Reported
Swelling; Synovitis;	Arava	S	Unknown	Not Reported
Therapeutic Response	Arthrotec	S	Unknown	Not Reported
Decreased; Wrist	Azathioprine	S	Unknown	Not Reported
Deformity	Celebrex	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Celecoxib	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Leflunomide	S	Unknown	Not Reported
Lyrica	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Not Reported
Methotrexate	S	Parenteral	Not Reported
Methotrexate	S	Unknown	Not Reported
Methotrexate	S	Oral	Not Reported
Misoprostol	S	Unknown	Not Reported
Naprosyn [Naproxen]	S	Unknown	Not Reported
Nifedipine	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Orencia	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Diclofenac Potassium	S	Unknown	Not Reported
Etanercept	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Winpred	S	Unknown	Not Reported
Tofacitinib	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17794311	EXPEDITED (15-DAY)	DE		IT-TEVA-2020-IT-1235086		77 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Erythema Multiforme; Neutrophilia; Off Label Use; Rash Erythematous	Darunavir			S	Oral	800 Mg		Teva	
	Plaquenil			S	Oral	400 Mg		Not Reported	
	Ritonavir Sandoz			S	Oral	100 Mg		Not Reported	
	Soldesam			C	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported	
	Bisoprolol Fumarate			C	Oral	1.25 Mg		Not Reported	
	Perindopril			C	Oral	5 Mg		Not Reported	
	Atorvastatin			C	Oral	40 Mg		Not Reported	
	Cardioaspirin			C		1 Dosage Form		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17805102	EXPEDITED (15-DAY)		OT	BR-ADVANSZ PHARMA-202005005322			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Asthenia; Malaise; Pain; Rheumatoid Arthritis; Rheumatoid Factor Quantitative Increased; Therapy Cessation	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia	
	Hydroxychloroquine			S	Oral	400 Mg, Qd		Concordia	
	Concor			C		Unk		Not Reported	
	Libian21			C				Not Reported	
	Rosuvastatin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17812623	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1049359		77 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Off Label Use	Lopinavir/Ritonavir			S	Oral	1 Gram, Qd		Not Reported	
	Plaquenil /00072602/			S	Oral	400 Milligram, Qd		Mylan	
	Roactemra			S	Intravenous (not otherwise specified)	640 Milligram, Total		Mylan	
	Ceftriaxone Disodium			C	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urbason Solub	C	Unknown	40 Milligram	Mylan
Dalacin C /00166001/	C	Unknown	Unk	Mylan
Kayexalate	C	Oral	28 Gram	Mylan
Magnesium Sulfate	C	Intravenous (not otherwise specified)	1 Gram	Mylan
Lasix /00032601/	C	Intravenous (not otherwise specified)	40 Milligram	Mylan
Heparin	C	Unknown	2500 Kilo-International Unit	Mylan
Clindamicina Fosfato	C	Unknown	1800 Milligram	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17842961	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606547			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Contraindicated Product Administered; Glossodynia; Maternal Exposure During Pregnancy; Pain; Pemphigus; Product Use Issue; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfate]				
Prednisone	S	Unknown		Not Reported
Simponi	S	Subcutaneous		Not Reported
Methotrexate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848251	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011212			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosis	Alendronate			S	Unknown	Unk		Apotex
	Prednisone			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Apotex
	Folic Acid			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Apotex
	Actemra			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Enbrel			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Phthalylsulfathiazole			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848291	EXPEDITED (15-DAY)		OT	CO-ABBVIE-19K-036-3214198-00			Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Chest Pain; Discomfort; Dizziness; Dry Eye; Dry Mouth; Eye Inflammation; Fibromyalgia; Gastritis; Hernia; Inflammation; Insomnia; Intervertebral Disc Protrusion; Mobility Decreased; Mobility Decreased; Nausea; Oropharyngeal Pain; Pain; Pelvic Floor Dysfunction; Spinal Pain; Tachycardia; Weight Increased	Humira 40mg/0.4ml Deflazacort Hydroxychloroquine	S S S	Subcutaneous Unknown Unknown	Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848306	EXPEDITED (15-DAY)		OT	CA-UCBSA-2020021830		40 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Cimzia			S	Subcutaneous	Unk		Not Reported
Arthralgia; Coeliac Disease; Condition Aggravated; Drug Ineffective; Fatigue; Grip Strength Decreased;	Actemra			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram		Not Reported
Headache; Hepatic Enzyme Increased;	Apo-Prednisone			S	Oral	1 Dosage Form, Once Daily (Qd)		Not Reported
Injection Site Reaction;	Arava			S		Unk		Not Reported
Joint Swelling; Loss Of Personal Independence In Daily Activities;	Enbrel			S	Subcutaneous	50 Milligram		Not Reported
Musculoskeletal Stiffness;	Gold			S		Unk		Not Reported
Nail Disorder; Off Label Use; Onychomycosis;	Humira			S	Subcutaneous	40 Milligram		Not Reported
Rheumatoid Arthritis; Treatment Failure	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	750 Milligram		Not Reported
	Prednisone			S	Oral	20 Milligram, Once Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					(Qd)				
	Remicade	S	Intravenous (not otherwise specified)	500 Milligram					Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	1000 Milligram, 2x/Day (Bid)					Not Reported
	Rituxan	S		1 Gram, 2x/Day (Bid)					Not Reported
	Rituximab	S		1000 Milligram, 2x/Day (Bid)					Not Reported
	Simponi	S		50 Milligram					Not Reported
	Sulfasalazine	S		Unk					Not Reported
	Tofacitinib Citrate	S		5 Milligram, 2x/Day (Bid)					Not Reported
	Xeljanz	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848313	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212639			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Pneumonia; Pulmonary Mass; Tinnitus	Methotrexate Sodium			S	Unknown			Pfizer
	Ibuprofen			S	Unknown			Pfizer
	Sulfasalazine			S	Unknown			Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisone			C	Unknown	5 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848330	EXPEDITED (15-DAY)		HO, OT	TR-IPCA LABORATORIES LIMITED-IPC-2020-TR-001729			Unknown	TUR

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Left Ventricular Dysfunction; Toxicity To Various Agents	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848351	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242648		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848377	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245897		75 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848404	EXPEDITED (15-DAY)		DE, OT	MX-ADVANSZ PHARMA-202005005679			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use	Hydroxychloroquine			S		200 Mg, Bid		Concordia	
	Hydroxychloroquine			S				Concordia	
	Methylprednisolone			C		Unk		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Clarithromycin			C		Unk		Not Reported	
	Enoxaparin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848419	EXPEDITED (15-DAY)		OT	JP-ADVANSZ PHARMA-GSH201908-001809			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Foetal Death	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg, Qd		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 Mg/Day Alternately		Concordia	
	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Oral	200 Mg/Day And 400 M/Day Alternately		Concordia	
	Prograf			C		Unk		Not Reported	
	Persantin			C		Unk		Not Reported	
	Prednisolone			C		Unk		Not Reported	
	Edirol			C		Unk		Not Reported	
	Edirol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848423	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2020-042737		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Nephrolithiasis; Somnolence; Visual Impairment	Orencia	S	Unknown	Unk	Bristol Myers Squibb
	Acetaminophen	S	Unknown	Unk	Not Reported
	Actemra	S	Unknown	Unk	Not Reported
	Apo-Acetaminophen	S	Unknown	325 Milligram	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	40 Milligram, Qwk	Not Reported
	Enbrel	S	Unknown	50 Milligram, Qd	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	200 Milligram, Bid	Not Reported
	Leflunomide	S	Oral	20 Milligram, Qd	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Rituximab	S	Intravenous drip	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Sulfasalazine	S	Oral	2000 Milligram	Not Reported
	Tylenol	S	Unknown	2000 Milligram	Not Reported
	Acetaminophen;Codeine Phosphate	C	Unknown	Unk	Not Reported
	Celebrex	C	Unknown	Unk	Not Reported
	Hydromorphone Hcl	C	Unknown	Unk	Not Reported
	Meloxicam	C	Unknown	Unk	Not Reported
	Methotrexate	C	Unknown	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Xeljanz	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848440	EXPEDITED (15-DAY)		DS	GB-IPCA LABORATORIES			Unknown	GBR

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LIMITED-IPC-2020-GB-001714

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Hypotension	Hydroxychloroquine			S	Unknown	800 Milligram		Ipca
	Mirabegron			C	Unknown	Unk		Not Reported
	Amoxicillin			C	Unknown	Unk		Not Reported
	Digoxin			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Adcal-D3			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Dabigatran			C	Unknown	Unk		Not Reported
	Alendronic Acid			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848564	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-042910			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Granuloma	Orencia			S	Unknown	780 Milligram, Qwk		Bristol Myers Squibb
	Actemra			S	Unknown	680 Milligram, Qwk		Not Reported
	Actemra			S	Unknown	360 Milligram, Qwk		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Milligram, 2 Every 1 Week		Not Reported
	Enbrel			S	Unknown	50 Milligram, 1 Every 1 Week		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Skin; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Panniculitis; Peripheral Swelling; Rash; Rash Pruritic; Rheumatoid Arthritis; Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Ulcer	Humira	S	Subcutaneous	40 Milligram, Q2wk	Not Reported
	Hydroxychloroquine Sulfate	S	Oral		Not Reported
	Leflunomide	S	Oral		Not Reported
	Methotrexate	S	Unknown	12 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	15 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	17.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Subcutaneous	10 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	12.5 Milligram, Qwk	Not Reported
	Methotrexate	S	Unknown	10 Milligram, Qwk	Not Reported
	Myochrysine	S	Intramuscular	50 Milligram, Qmo	Not Reported
	Remicade	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Unknown	100 Milligram, 2 Every 1 Day	Not Reported
	Sulfasalazine	S	Unknown		Not Reported
	Alendronate Sodium	C	Unknown	70 Milligram, Qwk	Not Reported
	Ciclosporin	C	Unknown	150 Milligram, 1 Every 24 Day	Not Reported
	Prednisone	C	Unknown	10 Milligram, Qd	Not Reported
	Xeljanz	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848600	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606568			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported
Alopecia; Arthropathy;	Rituximab			S	Intravenous drip			Not Reported
Fatigue; Glossodynia;	Tocilizumab			S	Unknown			Not Reported
Hand Deformity;	Cimzia			S	Subcutaneous			Not Reported
Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain;	Cortisone Acetate			S	Unknown			Not Reported

FDA Adverse Event Reporting System

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Pemphigus; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Diclofenac	S	Unknown	Not Reported
	Diclofenac Sodium	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848603	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANTZ PHARMA-202005005603			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine			S				Concordia

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Azithromycin	S	Unknown	Unknown	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
Tacrolimus	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848607	EXPEDITED (15-DAY)	HO		ES-ROCHE-2609953		72 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemolytic Anaemia; Hypofibrinogenaemia	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab			S				Not Reported
	Dolquine			S	Other	400 Mg Dia		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848609	EXPEDITED (15-DAY)	OT		CA-ROCHE-2606875			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Arthropathy; Contraindicated Product Administered; Discomfort; Drug Ineffective; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Rituxan			S	Unknown			Not Reported
	Tocilizumab			S	Subcutaneous			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cetirizine Hydrochloride			S				Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Cortisone Acetate			S	Topical			Not Reported
	Desoximetasone			S	Oral			Not Reported
	Diclofenac Sodium			S	Unknown			Not Reported
	Etanercept			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported

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Hydroxychloroquine	S	Unknown	Not Reported
Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Methotrexate	S	Intra-arterial	Not Reported
Methotrexate	S	Oral	Not Reported
Methotrexate Sodium	S	Unknown	Not Reported
Orencia	S	Subcutaneous	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Apo-Prednisone	S	Unknown	Not Reported
Simponi	S	Subcutaneous	Not Reported
Arava	S	Oral	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Adalimumab	S	Subcutaneous	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848664	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606545		45 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Confusional State; Contraindicated Product Administered; Contusion; Drug Ineffective; Dyspnoea; Fatigue; Folliculitis; Gastrointestinal Disorder; Hypersensitivity; Ill-Defined Disorder; Impaired Healing; Infection; Irritable Bowel	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Joint Swelling; Lower Respiratory Tract Infection; Muscle Injury; Nasopharyngitis; Off Label Use; Peripheral Swelling; Pruritus; Pyrexia; Rash; Sinusitis; Sleep Disorder Due To General Medical Condition, Insomnia Type; Stomatitis; Swelling; Therapeutic Product Effect Decreased; Weight Increased	Abatacept	S	Intravenous (not otherwise specified)	Not Reported
	Acetaminophen	S	Unknown	Not Reported
	Act Oxycodone Cr	S	Unknown	Not Reported
	Apo-Acetaminophen	S	Unknown	Not Reported
	Chlorhexidine	S	Unknown	Not Reported
	Chlorhexidine Gluconate	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate Sodium	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Oxycodone	S	Unknown	Not Reported
	Oxycodone Terephthalate	S	Unknown	Not Reported
	Oxycodone And Acetaminophen	S	Unknown	Not Reported
	Simponi	S	Periarticular	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Pantoprazole	C		Not Reported
	Pantoloc [Pantoprazole]	C		Not Reported
	Arava	C		Not Reported
	Cetirizine	C		Not Reported

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Hydroxychloroquine Sulfate			C				Not Reported		
Ibuprofen			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848793	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015772			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac			S	Unknown				Not Reported
Alopecia; Arthralgia; Blood	Desoximetasone			S	Oral				Not Reported
Cholesterol Increased;	Actemra			S	Unknown				Not Reported
Contraindicated Product	Apo Prednison			S	Unknown				Not Reported
Administered; Drug	Arava			S	Unknown				Not Reported
Ineffective; Exposure	Cetirizine Hydrochloride			S	Unknown				Not Reported
During Pregnancy;	Cimzia			S	Subcutaneous				Not Reported
General Physical Health	Cimzia			S					Not Reported
Deterioration; Headache;	Cortisone Acetate			S	Unknown				Not Reported
Hypersensitivity;	Enbrel			S	Subcutaneous				Not Reported
Hypertension; Joint	Folic Acid			S	Unknown				Not Reported
Swelling; Live Birth;	Fosamax			S	Unknown				Not Reported
Musculoskeletal Stiffness;	Humira			S	Subcutaneous				Not Reported
Pain; Pemphigus;	Hydroxychloroquine			S	Unknown				Not Reported
Pericarditis; Product Use	Hydroxychloroquine Sulfate			S	Unknown				Not Reported
Issue; Rheumatic Fever;	Methotrexate			S	Unknown				Not Reported
Rheumatoid Arthritis;	Methotrexate			S	Subcutaneous				Not Reported
Swelling; Swollen Joint	Methotrexate			S	Oral				Not Reported
Count Increased;	Orencia			S	Unknown				Not Reported
Synovitis; Systemic Lupus	Orencia			S	Intravenous (not otherwise specified)				Not Reported
Erythematosis;	Phthalylsulfathiazole			S	Unknown				Not Reported
Therapeutic Product Effect	Plaquenil			S	Unknown				Not Reported
Decreased; Treatment	Prednisone			S	Unknown				Not Reported
Failure; Type 2 Diabetes Mellitus									

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	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Unknown	Not Reported
	Salazopyrine	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848962	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606933		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Infection; Intentional Product Use Issue; Nausea; Nodule; Off Label Use; Product Use Issue; Rheumatoid Arthritis	Actemra			S	Unknown			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Risedronate Sodium			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17848987	EXPEDITED (15-DAY)		OT	ES-SA-2020SA138605			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatitis; Off Label Use	Hydroxychloroquine	S	Oral	400 Mg, Qd	Sanofi
	Hydroxychloroquine	S			Sanofi
	Ivermectin	S	Oral	12 Mg, 1x	Sanofi
	Enoxaparin Sodium	S	Intravenous (not otherwise specified)	40 Mg, Qd	Sanofi
	Tocilizumab	S	Intravenous (not otherwise specified)	600 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849009	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606523			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Drug Ineffective; Intentional Product Use Issue; Maternal Exposure During Pregnancy; Off Label Use; Pain; Pemphigus; Rheumatoid Arthritis; Systemic Lupus Erythematosus	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Apo-Folic Acid			S	Unknown			Not Reported
	Apo-Hydroxyquine			S	Unknown			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cortisone Acetate			S	Unknown			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate Sodium			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Phthalylsulfathiazole			S	Unknown			Not Reported

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Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849022	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANS PHARMA-202005005919			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849023	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANS PHARMA-202005005785			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849024	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		15 YR	Female	USA

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2020R1-248623

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Level Increased; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Product Use Issue	Hydroxychloroquine			S	Unknown	Unk (10-11 Grams)		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849041	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA- 202004004635			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Adalimumab			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849042	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA- 202005005915			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported

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Azithromycin	S	Unknown	Unk	Not Reported
Tacrolimus	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849068	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANZ PHARMA-202005005913			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Unk, Tablet		Concordia
	Hydroxychloroquine			S				Concordia
	Prednisone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Belatacept			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849105	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606333			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Drug Ineffective; Ill-Defined Disorder; Loss Of Consciousness; Mobility Decreased; Off Label Use	Actemra			S	Subcutaneous			Not Reported
	Anakinra			S	Subcutaneous			Not Reported
	Arava			S	Oral			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

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Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849173	EXPEDITED (15-DAY)		OT	CA-ROCHE-2605500		70 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported	
Arthralgia; Bone Graft;	Arava			S	Unknown			Not Reported	
Condition Aggravated;	Methotrexate			S	Unknown			Not Reported	
Drug Ineffective; Drug	Methotrexate			S	Oral			Not Reported	
Intolerance; Eye Disorder;	Methotrexate			S	Subcutaneous			Not Reported	
Foot Operation; Herpes	Orencia			S	Unknown			Not Reported	
Zoster; Joint Swelling;	Orencia			S	Unknown			Not Reported	
Limb Discomfort; Malaise;	Orencia			S	Unknown			Not Reported	
Nausea; Nodule; Off Label	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported	
Use; Osteoarthritis; Rectal	Sulfate]			S	Unknown			Not Reported	
Haemorrhage; Thyroid	Sulfasalazine			S	Unknown			Not Reported	
Cancer	Xeljanz			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849175	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANS PHARMA-202005005788			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Hydroxychloroquine			S	Unknown	Unknown		Concordia	
Covid-19; Off Label Use	Prednisone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unknown		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849272	EXPEDITED (15-DAY)		OT	CA-ROCHE-2612226		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Renal Failure	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849374	EXPEDITED (15-DAY)		HO, LT, OT	US-ADVANSZ PHARMA-202005005916			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Covid-19; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Prednisone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849523	EXPEDITED (15-DAY)			US-ADVANSZ PHARMA-202004004125			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Peripheral Swelling; Product Availability Issue; Unevaluable Event	Hydroxychloroquine			S		Decreased Dose		Concordia	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849592	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020211375		59 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Multiple Organ Dysfunction Syndrome; Off Label Use	Cefepime Hcl			S		Unk		Pfizer
	Cefepime Hcl			S				Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Linezolid			S		Unk		Pfizer
	Linezolid			S				Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk (Ds)		Pfizer
	Sulfamethoxazole/Trimethoprim			S				Pfizer
	Tobramycin			S		Unk		Pfizer
	Tobramycin			S				Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Vancomycin Hcl			S				Pfizer
	Hydroxychloroquine			S		400 Mg, 2x/Day(On Day 0)		Not Reported
	Hydroxychloroquine			S		200 Mg, Daily(For Days 1-4)		Not Reported
	Oseltamivir			S		Unk		Not Reported
	Oseltamivir			S				Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)	400 Mg, Single (1 Dose)		Not Reported
	Lopinavir + Ritonavir			S		400 Mg, 2x/Day		Not Reported
	Lopinavir + Ritonavir			S				Not Reported
	Tacrolimus			C		6 Mg, 2x/Day(With Goal Trough Level Of 4-6 Ng/MI)		Not Reported
	Tacrolimus			C		Unk(60% Dose Reduction)		Not Reported
	Mycophenolic Acid			C		360 Mg, 2x/Day		Not Reported
	Immunoglobulin [Immunoglobulin Human Normal]			C	Intravenous (not otherwise specified)	10 G, Single		Not Reported
	Norepinephrine			C		Unk		Not Reported
	Micafungin			C		100 Mg, Daily		Not Reported
	Heparin			C	Intravenous drip	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849690	EXPEDITED (15-DAY)		HO, LT, OT	CA-APOTEX-2017AP007784		27 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Autoimmune Disorder; Cognitive Disorder; Cushing'S Syndrome; Headache; Infusion Related Reaction; Leukopenia; Muscular Weakness; Paralysis; Proteinuria; Psychotic Disorder; Therapeutic Response Decreased	Apo-Azathioprine			S	Unknown	100 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	50 Mg, Qd		Not Reported
	Apo-Azathioprine			S	Unknown	20 Mg, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported
	Prednisone			S	Unknown	20 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Apotex
	Cellcept /01275102/			S	Unknown			Not Reported
	Procytox			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Procytox			S	Unknown	500 Mg, Q.O.Wk.		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	1000 Mg, Q.O.Wk.		Not Reported
	Rituxan			S				Not Reported
	Diphenhydramine Hydrochloride			C	Oral	50 Mg, Unk		Not Reported
	Acetaminophen			C	Oral	1000 Mg, Unk		Not Reported
	Acetaminophen			C	Unknown	100 Mg, Qd		Not Reported
	Methylprednisolone Sodium Succinate			C	Intravenous (not otherwise specified)	Unk, Bid		Not Reported
	Methylprednisolone Sodium Succinate			C	Unknown	Unk, Bid		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849861	EXPEDITED (15-DAY)		DE, OT	ES-ABBVIE-20K-144-3426262-00		64 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Covid-19 Pneumonia; Hepatitis Cholestatic	Kaletra 200/50			S	Oral			Not Reported
	Azitromicina			S	Oral			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxicloroquina Sulfato			S	Oral			Not Reported
	Interferon Beta-1a			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17849988	EXPEDITED (15-DAY)		DS, HO	CA-ROCHE-2606400		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Basal Cell Carcinoma; Blood Parathyroid Hormone Decreased; C-Reactive Protein Increased; Drug Eruption; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Enthesopathy; Erythema; Granuloma Skin; Headache; Hypercalcaemia; Inflammation; Infusion Related Reaction; Loss Of Personal Independence In Daily Activities; Nausea; Panniculitis; Peripheral Swelling; Psoriatic Arthropathy; Rash; Rash Pruritic; Red Blood Cell Sedimentation Rate; Rheumatoid Arthritis;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Tocilizumab			S	Unknown			Not Reported
	Apo-Ibuprofen			S	Oral			Not Reported
	Apremilast			S	Oral			Not Reported
	Apremilast			S				Not Reported
	Apremilast			S				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			S	Unknown			Not Reported
	Ciclosporin			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Codeine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous			Not Reported
	Humira			S				Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Nodule; Skin Necrosis; Skin Ulcer; Synovitis; Tendonitis; Tenosynovitis; Tongue Disorder; Ulcer	Hydroxychloroquine Sulfate	S		Not Reported
	Infliximab	S	Oral	Not Reported
	Infliximab	S		Not Reported
	Leflunomide	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Motrin [Ibuprofen]	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Otezla	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Endocervical	Not Reported
	Stelara	S	Subcutaneous	Not Reported
	Alendronate Sodium	S	Unknown	Not Reported
	Colchicine	C	Unknown	Not Reported
	Dexilant	C	Oral	Not Reported
	Febuxostat	C		Not Reported
	Folic Acid	C		Not Reported
	Gravol	C		Not Reported
	Mogadon	C	Oral	Not Reported
	Nitrazepam	C	Oral	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850007	EXPEDITED (15-DAY)		HO	ES-ACCORD-183641		81 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Hydroxychloroquine			S	Oral	400 Mg Day		Not Reported	
Hepatic Encephalopathy;	Amoxicillin/Clavulanic Acid			S	Intravenous (not	1 Gr Every 12 Hours X 5		Not Reported	
Off Label Use;					otherwise specified)	Days Followed By 1gr			
Pancytopenia						Every 8 Hours X 6 Days			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850039	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015789		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown			Not Reported	
Alopecia; Arthropathy;	Desoximetason			S	Oral			Not Reported	
Exposure During	Actemra			S	Oral			Not Reported	
Pregnancy; Fatigue;	Arava			S	Oral			Not Reported	
Glossodynia; Hand	Cetirizine Hydrochloride			S	Unknown			Not Reported	
Deformity; Off Label Use;	Cimzia			S	Subcutaneous			Not Reported	
Pain; Pemphigus;	Cortisone Acetate			S	Unknown			Not Reported	
Rheumatoid Arthritis;	Enbrel			S	Subcutaneous			Not Reported	
Swelling; Systemic Lupus	Folic Acid			S	Unknown			Not Reported	
Erythematous; Wound	Fosamax			S	Oral			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Oral	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850043	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015774		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac Sodium			S	Unknown	Not Specified		Not Reported
Alopecia; Anti-Cyclic	Hydrocortisone Acetate			S	Subcutaneous			Valeant
Citrullinated Peptide	Hydrocortisone			S	Oral			Valeant
Antibody Positive;	Topicort			S	Subcutaneous			Not Reported
Arthropathy; Condition	Topicort			S	Unknown			Not Reported
Aggravated;	Actemra			S	Unknown			Not Reported
Contraindicated Product	Apo-Prednisone			S	Unknown			Not Reported
Administered; Discomfort;	Arava			S	Oral			Not Reported
Drug Ineffective; Drug	Cetirizine Hydrochloride			S	Unknown			Not Reported
Intolerance; Fatigue;	Cetirizine Hydrochloride			S	Unknown			Not Reported
Glossodynia; Hand	Cetirizine Hydrochloride And			S	Unknown			Not Reported
Deformity; Hepatic	Pseudoephedrine							
Enzyme Increased;	Cetirizine Hydrochloride And			S				Not Reported
Hypersensitivity; Infusion	Pseudoephedrine							
Related Reaction; Joint								
Swelling; Maternal								
Exposure During								
Pregnancy; Pain;								
Pemphigus; Pericarditis;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use Issue; Rash; Rheumatoid Arthritis; Rheumatoid Factor Positive; Swelling; Synovitis; Systemic Lupus Erythematosis; Wound	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Unknown	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Oral	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Golimumab	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil	S	Oral	Not Reported
	Prednisone	S	Unknown	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Sarilumab	S	Unknown	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Stelara	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfasalazine	S	Oral	Not Reported
Xeljanz	S	Unknown	Not Reported
Salazopyrin	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported
Tofacitinib Citrate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850045	EXPEDITED (15-DAY)		DS, OT	CA-BAUSCH-BL-2020-015778		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diclofenac			S	Unknown			Not Reported
Alopecia; Anti-Cyclic	Topicort			S	Cutaneous			Not Reported
Citrullinated Peptide	Actemra			S	Subcutaneous	Not Specified		Not Reported
Antibody Positive;	Alendronate Sodium			S	Oral			Not Reported
Arthropathy;	Arava			S	Oral			Not Reported
Contraindicated Product	Cetirizine Hydrochloride			S	Unknown			Not Reported
Administered; Discomfort;	Desoximetasone			S	Oral			Not Reported
Drug Ineffective; Drug	Cetirizine Hydrochloride And			S	Unknown			Not Reported
Intolerance; Duodenal	Pseudoephedrine Hydrochloride			S	Subcutaneous			Not Reported
Ulcer Perforation; Fatigue;	Cimzia			S	Subcutaneous			Not Reported
Glossodynia; Hand	Enbrel			S	Subcutaneous			Not Reported
Deformity; Helicobacter	Folic Acid			S	Unknown			Not Reported
Infection; Hepatic Enzyme	Folic Acid			S	Unknown			Not Reported
Increased;	Humira			S	Subcutaneous			Not Reported
Hypersensitivity; Infusion	Hydroxychloroquine			S	Unknown			Not Reported
Related Reaction;	Hydroxychloroquine			S	Oral			Not Reported
Maternal Exposure During	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Pregnancy; Pain;	Leflunomide			S	Oral			Not Reported
Pemphigus; Pericarditis;								
Rash; Rheumatoid								
Arthritis; Swelling;								
Synovitis; Systemic Lupus								
Erythematous; Wound								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methotrexate	S	Oral	Not Reported
Methotrexate	S	Oral	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Not Reported
Phthalylsulfathiazole	S	Unknown	Not Reported
Plaquenil	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituxan	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Sulfathalidine	S	Oral	Not Reported
Tofacitinib	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported
Cortisone Acetate	S	Topical	Not Reported
Salazopyrin	C	Unknown	Not Reported
Atasol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850050	EXPEDITED (15-DAY)		DS	CA-BAUSCH-BL-2020-015793		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Topicort			S	Cutaneous			Not Reported
Adverse Event; Alopecia;	Diclofenac Sodium			S	Unknown			Not Reported
Anti-Cyclic Citrullinated Peptide Antibody Positive;	Actemra			S	Subcutaneous			Not Reported
Arthropathy; Discomfort;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Duodenal Ulcer Perforation; Fatigue; Glossodynia; Hand Deformity; Helicobacter Infection; Hepatic Enzyme Increased; Hypersensitivity; Infusion Related Reaction; Pain; Pemphigus; Pericarditis; Pregnancy; Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Apo-Hydroxyquine	S	Unknown	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Hydrochloride;Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			
	Cimzia	S	Subcutaneous	Not Reported
	Cortisone Acetate	S	Topical	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Remicade	S	Intravenous (not otherwise specified)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfasalazine	S	Oral	Not Reported
Sulfathalidine	S	Unknown	Not Reported
Tofacitinib Citrate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850058	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015796		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Desoximetasone			S	Oral			Not Reported
Alopecia; Condition	Diclofenac			S	Unknown			Not Reported
Aggravated; Drug	Actemra			S	Unknown			Not Reported
Ineffective; Drug	Apo-Prednisone			S	Unknown			Not Reported
Intolerance; Fatigue;	Arava			S	Oral			Not Reported
Glossodynia; Hand	Cetirizine Hydrochloride			S	Unknown			Not Reported
Deformity; Maternal	Cimzia			S	Subcutaneous			Not Reported
Exposure During	Cortisone Acetate			S	Unknown			Not Reported
Pregnancy; Off Label Use;	Enbrel			S	Subcutaneous			Not Reported
Pain; Pemphigus;	Folic Acid			S	Unknown			Not Reported
Swelling; Systemic Lupus	Fosamax			S	Unknown			Not Reported
Erythematousus	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Phthalylsulfathiazole	S	otherwise specified)	Not Reported
Plaquenil	S	Unknown	Not Reported
Remicade	S	Oral	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
Rituxan	S	Oral	Not Reported
Xeljanz	S	Intravenous (not otherwise specified)	Not Reported
	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850061	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-015809		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blood Pressure Increased; Cataract; Diarrhoea; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Eye Disorder; Glaucoma; Hernia; Herpes Zoster; Insomnia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Nasopharyngitis; Off Label Use; Pain In Extremity; Peripheral Swelling; Therapeutic Product Effect Decreased	Desoximetasone			S	Unknown			Not Reported
	Glumetza			S	Unknown			Santarus
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe, Subcutaneous Solution		Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown	Powder For Solution Intravenous		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Oral	Not Reported
Acetaminophen	C	Unknown	Not Reported
Altace	C	Unknown	Not Reported
Arava	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported
Codeine	C	Unknown	Not Reported
D-Alpha Tocopherol	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Prednisone	C	Oral	Not Reported
Rosuvastatin Calcium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850062	EXPEDITED (15-DAY)		DS	CA-BAUSCH-BL-2020-015814		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Topicort			S	Cutaneous			Not Reported
Adverse Event; Alopecia;	Diclofenac Sodium			S	Unknown			Not Reported
Anti-Cyclic Citrullinated	Actemra			S	Subcutaneous	Not Specified		Not Reported
Peptide Antibody Positive;	Apo-Hydroxyquine			S	Unknown			Not Reported
Arthropathy; Discomfort;	Apo-Prednisone			S	Unknown			Not Reported
Drug Ineffective; Drug	Arava			S	Oral			Not Reported
Intolerance; Duodenal	Cetirizine Hydrochloride			S	Unknown			Not Reported
Ulcer Perforation; Fatigue;	Cetirizine			S	Unknown			Not Reported
Glossodynia; Hand	Hydrochloride;Pseudoephedrine							
Deformity; Helicobacter	Hydrochloride							
Infection; Hepatic Enzyme	Cetirizine			S	Unknown			Not Reported
Increased;	Hydrochloride							
Hypersensitivity; Infusion	Hydrochloride							
Related Reaction;	Cetirizine			S	Unknown			Not Reported
Maternal Exposure During	Hydrochloride;Pseudoephedrine							
Pregnancy; Pain;	Hydrochloride							
Pemphigus; Pericarditis;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Rheumatoid Arthritis; Swelling; Synovitis; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Oral	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Leflunomide	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil (Hydroxychloroquine Sulfate)	S	Oral	Not Reported
	Prednisone	S	Oral	Not Reported
	Pseudoephedrine Hydrochloride	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Sulfathalidine	S	Unknown	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported
	Cortisone Acetate	S	Topical	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850071	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606989		64 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock; Arthralgia; Bedridden; Condition Aggravated; Drug Ineffective; Fibromyalgia; Foot Fracture; General Physical Health Deterioration; Hepatitis; Loss Of Personal Independence In Daily Activities; Lower Limb Fracture; Mobility Decreased; Myocardial Infarction; Off Label Use; Osteoporosis; Rheumatoid Arthritis; Therapeutic Product Effect Incomplete; Treatment Failure	Actemra			S	Unknown			Not Reported
	Apo-Lefflunomide			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Risedronate Sodium			S	Unknown			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850123	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212816			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Osteoporosis	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Unknown	5 Mg		Pfizer
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported

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Mycophenolate Mofetil

S

Unknown

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850127	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212675		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Abnormal; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Red Blood Cell Sedimentation Rate Abnormal; Synovitis; X-Ray Abnormal	Enbrel			S	Unknown	50 Mg		Unknown
	Methotrexate Sodium			S	Oral	17 Mg		Pfizer
	Methotrexate Sodium			S	Oral	25 Mg, Daily		Pfizer
	Sulfasalazine			S	Unknown	1.5 G, 2x/Day		Pfizer
	Actemra			S	Unknown	Unk		Not Reported
	Cimzia			S	Subcutaneous	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	400 Mg		Not Reported
	Penicillin G [Benzylpenicillin]			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Not Reported
	Calcium			C		Unk		Not Reported
	Hydroxychloroquine			C	Unknown	300 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	300 Mg		Not Reported
	Prednisone			C	Unknown	10 Mg, Daily		Not Reported
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported
	Xeljanz			C	Oral	5 Mg, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850129	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020212802		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

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Blindness Unilateral;	Methotrexate Sodium	S	Unknown	Unk	Pfizer
Condition Aggravated;	Xeljanz	S	Unknown	5 Mg, 2x/Day	Pfizer
Drug Ineffective; Drug	Arava	S	Unknown	Unk	Not Reported
Intolerance; Herpes	Humira	S	Subcutaneous	Unk	Not Reported
Zoster; Hypertension;	Plaquenil S	S	Unknown	Unk	Not Reported
Inflammation; Joint	Enbrel	C	Unknown	Unk	Not Reported
Swelling; Musculoskeletal	Prednisone	C	Unknown		Not Reported
Disorder; Musculoskeletal					
Stiffness; Pain;					
Pancreatitis; Peripheral					
Swelling; Pneumonia;					
Psoriatic Arthropathy; Scar					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850130	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020212633		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Back Pain;	Methotrexate Sodium			S	Subcutaneous	20 Mg, 1 Every 1 Weeks		Pfizer
Condition Aggravated;	Enbrel			S	Subcutaneous	50 Mg		Unknown
Drug Ineffective; Fatigue;	Sulfasalazine			S	Unknown	20 Mg, 2 Every 1 Days		Pfizer
Joint Swelling; Loss Of	Actemra			S	Unknown			Not Reported
Personal Independence In	Arava			S	Unknown	20 Mg, 1 Every 24 Hours		Not Reported
Daily Activities; Pain;	Humira			S	Subcutaneous	20 Mg, 1 Every 24 Hours		Not Reported
Peripheral Swelling;	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, 2 Every 1 Days		Not Reported
Rheumatoid Arthritis	Orencia			S	Unknown			Not Reported
	Prednisone			S	Oral	50 Mg, 1 Every 24 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850170	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP006658		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Apo-Azathioprine			S	Unknown	Unk		Not Reported
Blood Cholesterol	Apo-Leflunomide			S	Unknown	Unk		Apotex
Increased; C-Reactive								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Protein Abnormal; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Off Label Use; Rash; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Methotrexate	S	Oral	Unk	Not Reported
	Hydroxychloroquine	S	Unknown	2000 Mg, Unk	Apotex
	Hydroxychloroquine	S	Unknown	Unk	Apotex
	Arava	S	Unknown	Unk	Not Reported
	Enbrel	S	Subcutaneous	50 Mg, Q.Wk.	Not Reported
	Humira	S	Subcutaneous	40 G, Q.O.Wk.	Not Reported
	Humira	S	Subcutaneous	40 Mg, Bid	Not Reported
	Humira	S	Subcutaneous	40 Mg, Unk	Not Reported
	Orencia	S	Subcutaneous	750 Mg, Q.Wk.	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	2000 Mg, Unk	Not Reported
	Sulfasalazine	S	Unknown	Unk	Not Reported
	Plaquenil /00072602/	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	50 Mg, Bid	Not Reported
	Methotrexate	S	Parenteral	Unk	Not Reported
	Methotrexate	S	Subcutaneous	Unk	Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Methotrexate	S	Other	Unk	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	2000 Mg, Unk	Not Reported
	Xeljanz	C	Oral	50 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850185	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606520		49 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arthropathy; Condition	Actemra			S	Unknown				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggravated; Drug Hypersensitivity; Finger Deformity; Peripheral Swelling; Rash; Tenosynovitis; Treatment Failure; Urticaria	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Arava	S	Unknown	Not Reported
	Codeine	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Rocuronium Bromide	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850265	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606469			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Allergy To Chemicals; Arthralgia; Bone Density Decreased; C-Reactive Protein Increased; Crepitations; Deformity; Diarrhoea; Dizziness; Drug Ineffective; Drug Intolerance; Dry Eye; Fatigue; Feeling Abnormal; Fibromyalgia; Hand Deformity; Joint Range Of Motion Decreased; Joint Swelling; Liver Disorder; Malaise; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Stiffness; Myalgia; Off Label Use;	Actemra			S	Subcutaneous			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Meloxicam			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Mobicox			S	Unknown			Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pain In Extremity;
Peripheral Swelling;
Pulmonary Toxicity; Rash
Maculo-Papular; Rash
Pruritic; Rheumatoid
Arthritis; Rheumatoid
Nodule; Synovial Cyst;
Tenosynovitis;
Therapeutic Product Effect
Decreased; Upper
Respiratory Tract
Infection; White Blood Cell
Count Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850357	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020214596			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis;	Methotrexate Sodium			S	Oral	Unk		Pfizer	
Arthrodesis; Asthma;	Sulfasalazine			S	Unknown	1000 Mg, 2x/Day		Pfizer	
Coordination Abnormal;	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer	
Dry Eye; Gastrointestinal	Cimzia			S	Unknown	200 Mg, 1 Every 2 Weeks		Not Reported	
Disorder; Nausea;	Cimzia			S	Unknown	200 Mg, 1 Every 2 Weeks		Not Reported	
Palpitations;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
Photosensitivity Reaction;	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
Rash; Treatment Failure	Leflunomide			S	Unknown	20 Mg, 1x/Day		Not Reported	
	Leflunomide			S	Unknown	10 Mg, 1x/Day		Not Reported	
	Arava			C	Unknown			Not Reported	
	Depo-Medrol			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown	40 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850417	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020212807			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Interstitial Lung Disease	Methotrexate Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Xeljanz			S		Unk		Pfizer	
	Actemra			S		Unk		Not Reported	
	Arava			S		20 Mg, 1x/Day		Not Reported	
	Hydroxychloroquine			S		200 Mg, 1x/Day		Not Reported	
	Orencia			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850433	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241768		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported	
	Enoxaparina (2482a)			S	Subcutaneous	60 Mg		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850438	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242746		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850525	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242831			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

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Piroxicam	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850535	EXPEDITED (15-DAY)	OT		CA-TEVA-2020-CA-1242908		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Contraindicated Product Administered; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850537	EXPEDITED (15-DAY)	OT		CA-PFIZER INC-2020212789		57 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug	Enbrel			S	Unknown	Unk		Unknown

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Intolerance; Herpes Zoster; Hypertension; Pneumonia	Methotrexate Sodium	S	Unknown	Unk	Pfizer
	Xeljanz	S	Oral	5 Mg, 1 Every 12 Hours	Pfizer
	Arava	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850545	EXPEDITED (15-DAY)		HO, LT	IT-ACCORD-183867		88 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gamma-Glutamyltransferase Increased; Hypertransaminasaemia; Off Label Use	Hydroxychloroquine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850620	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426267-00		57 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Hyperbilirubinaemia	Kaletra 200/50			S	Oral			Not Reported
	Dolquine			S	Oral			Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850703	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606929			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue;	Actemra			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glossodynia; Off Label Use; Pemphigus; Systemic Lupus Erythematosus	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Apo-Prednisone	S	Unknown	Not Reported
	Apo-Prednisone	S		Not Reported
	Arava	S	Oral	Not Reported
	Cetirizine Hydrochloride	S	Unknown	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Unknown	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Simponi	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850889	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606964			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Actemra			S	Unknown			Not Reported	
Alopecia; Contraindicated	Rituxan			S	Intravenous drip			Not Reported	
Product Administered;	Arava			S	Oral			Not Reported	
Discomfort; Drug	Cetirizine Hydrochloride			S	Unknown			Not Reported	
Ineffective; Drug									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Fatigue; Glossodynia; Hand Deformity; Maternal Exposure During Pregnancy; Pemphigus; Product Use Issue; Rash; Rheumatoid Arthritis; Swelling; Systemic Lupus Erythematosus; Wound	Cimzia	S	Subcutaneous	Not Reported
	Desoximetasone	S	Oral	Not Reported
	Enbrel	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Fosamax	S	Oral	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Intravenous (not otherwise specified)	Not Reported
	Orencia	S	Subcutaneous	Not Reported
	Phthalylsulfathiazole	S	Unknown	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Tofacitinib Citrate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850911	EXPEDITED (15-DAY)		DE	MX-ADVANSZ PHARMA- 202005005727			Unknown	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Respiratory Disorder	Hydroxychloroquine			S		200 Mg, Bid		Concordia
	Hydroxychloroquine			S				Concordia
	Clarithromycin			C		Unk		Not Reported
	Ceftriaxone			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850937	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242799		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva	
	Mycophenolate Mofetil			S	Unknown	1440 Milligram Daily;		Not Reported	
	Cyclophosphamide			S	Unknown	150 Milligram Daily;		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400 Milligram Daily;		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Cymbalta			C	Unknown			Not Reported	
	Domperidone			C	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851322	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242756		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Joint Swelling; Psoriatic Arthropathy; Rheumatoid Arthritis; Sciatica; Sinusitis; Swelling	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	otherwise specified)	Not Reported
Simponi	S	Intravenous (not otherwise specified)	Not Reported
Sulfasalazine	S	Subcutaneous	Not Reported
		Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851324	EXPEDITED (15-DAY)		OT	NVSC2020US151019			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Hydroxychloroquine Sulfate Tablets USP			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851342	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242665		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Cough; Drug Intolerance; Dyspnoea; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Pulmonary Function Test Decreased; Therapy Non-Responder; Treatment Failure	Mycophenolate Mofetil			S	Oral			Teva
	Mycophenolate Mofetil			S				Teva
	Hydroxychloroquine Sulfate			S	Unknown	400 Milligram Daily;		Not Reported
	Mycophenolate Sodium			S	Unknown	1440 Milligram Daily;		Not Reported
	Procytox			S	Intravenous (not otherwise specified)	150 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S				Not Reported
	Cymbalta			C	Unknown			Not Reported
	Domperidone			C	Unknown			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851365	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242757		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Actemra			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851480	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242848			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma	Mycophenolate Mofetil			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851483	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-			Female	CAN

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1242904

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete; Treatment Failure	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Sulfasalazine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Remicade			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Actemra			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851519	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242888			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Intolerance; Psoriatic	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthropathy; Rash; Red Blood Cell Sedimentation Rate Increased; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Actemra	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Lyrica	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Piroxicam	C		Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851520	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242758		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Multiple Allergies; Musculoskeletal Pain; Psoriatic Arthropathy; Rash; Sinusitis; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rituximab	S	Intravenous drip	Not Reported
Simponi	S	Subcutaneous	Not Reported
Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851523	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1242818			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Psoriatic Arthropathy; Rash; Rheumatoid Arthritis; Sciatica; Sinusitis; Therapeutic Product Effect Incomplete	Mycophenolate Mofetil			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Actemra			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Enbrel			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Lyrica			S	Oral			Not Reported
	Orencia			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Simponi			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Piroxicam			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851555	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1242208		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hypokalaemia; Hypotension; Intentional Overdose; Tachycardia	Hydroxychloroquine	S	Oral	Approximately 10-11 Gram	Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851573	EXPEDITED (15-DAY)		OT	NVSC2020US151024			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851592	EXPEDITED (15-DAY)		OT	NVSC2020US151023			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Hydroxychloroquine Sulfate Tablets Usp			S	Transplacental	Maternal Dose: Unk		Novartis
	Betamethasone			S	Transplacental	Maternal Dose: Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851593	EXPEDITED (15-DAY)		DE	CA-ROCHE-2610888		36 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apparent Death; Bone Erosion; C-Reactive Protein Abnormal; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective; Intentional Product Use Issue; Intestinal Sepsis;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Unknown			Not Reported

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Joint Swelling; Myocardial Infarction; Off Label Use; Osteoarthritis; Pain;	Actemra	S	Unknown	Not Reported
Pulmonary Embolism;	Doxycycline Hyclate	S	Unknown	Not Reported
Pulmonary Thrombosis;	Enbrel	S	Unknown	Not Reported
Red Blood Cell Sedimentation Rate	Humira	S	Subcutaneous	Not Reported
Increased; Renal Failure; Rheumatoid Arthritis;	Humira	S	Unknown	Not Reported
Rheumatoid Factor	Hydroxychloroquine Sulfate	S	Unknown	Not Reported
Positive; Sepsis; Synovitis; Terminal State;	Leflunomide	S	Unknown	Not Reported
Thrombosis	Methotrexate	S	Unknown	Not Reported
	Orencia	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported
	Sodium Aurothiomalate	S		Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851594	EXPEDITED (15-DAY)		OT	CA-ROCHE-2610044			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rheumatoid Arthritis	Rituximab			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Orencia			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Methotrexate			C				Not Reported
	Prednisone			C				Not Reported

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Simponi		C		Not Reported					
Xeljanz		C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851614	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606970		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anti-Cyclic Citrullinated Peptide Antibody Positive; Arthropathy; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Foot Deformity; Hand Deformity; Hypertension; Infection; Intentional Product Use Issue; Loss Of Consciousness; Mobility Decreased; Nausea; Nodule; Off Label Use; Pulmonary Fibrosis; Red Blood Cell Sedimentation Rate Abnormal; Rheumatoid Factor Positive; Synovitis	Actemra			S	Subcutaneous			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Actonel			S	Unknown			Not Reported	
	Anakinra			S	Subcutaneous			Not Reported	
	Arava			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Gold			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral			Not Reported	
	Orencia			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Xeljanz			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851659	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020206955		42 YR	Male	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Hydroxyzine Hydrochloride			S	Intravenous (not otherwise specified)	25 Mg Every 6 Hours		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, Every 12 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851672	EXPEDITED (15-DAY)		HO	CA-PFIZER INC- 2020212770			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Ineffective; Musculoskeletal Pain; Nausea; Neck Pain; Pain In Extremity; Rash; Therapeutic Product Effect Decreased; Treatment Failure; Weight Decreased	Codeine			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg		Pfizer
	Humira			S	Subcutaneous	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Rituximab			S	Endocervical	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851707	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606940		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue; Gait Disturbance; Loss Of Personal Independence In Daily Activities; Neurogenic Bladder; Pollakiuria; Product Dose Omission	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Actemra			S	Subcutaneous			Not Reported
	Apo-Leflunomide			S	Oral			Not Reported
	Apo-Prednisone			S	Unknown			Not Reported

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	Arava	S	Oral	Not Reported
	Cimzia	S	Subcutaneous	Not Reported
	Folic Acid	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Hydroxychloroquine Sulfate	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851753	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609779			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Rheumatoid Arthritis; Treatment Failure	Tocilizumab			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851764	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426540-00		59 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Long Qt Syndrome	Kaletra 200/50			S	Oral			Not Reported	
	Dolquine			S	Oral			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Ceftriaxona			C	Intravenous (not otherwise specified)			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851794	EXPEDITED (15-DAY)		HO	CA-ROCHE-2606340			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adrenal Insufficiency;	Actemra			S	Intravenous (not			Not Reported
Antibody Test Positive;					otherwise specified)			
Arthritis; Arthropathy;	Anakinra			S	Subcutaneous			Not Reported
Body Height Below	Enbrel			S	Subcutaneous			Not Reported
Normal; Bone Density	Enbrel			S	Subcutaneous			Not Reported
Decreased; C-Reactive	Humira			S	Subcutaneous			Not Reported
Protein Increased;	Hydroxychloroquine Sulfate			S	Oral			Not Reported
Condition Aggravated;	Infliximab			S	Intravenous (not			Not Reported
Diarrhoea; Dizziness;					otherwise specified)			
Drug Ineffective; Drug	Infliximab			S	Unknown			Not Reported
Intolerance; Drug Specific								
Antibody; Human	Infliximab			S	Subcutaneous			Not Reported
Antichimeric Antibody	Methotrexate			S	Unknown			Not Reported
Positive; Intentional	Naproxen			S	Unknown			Not Reported
Product Use Issue;	Orencia			S	Intravenous (not			Not Reported
Juvenile Idiopathic					otherwise specified)			
Arthritis; Loss Of Personal	Prednisone			S	Oral			Not Reported
Independence In Daily	Prednisone			S	Oral			Not Reported
Activities; Mobility	Sulfasalazine			S	Oral			Not Reported
Decreased; Nausea;	Triamcinolone			S	Unknown			Not Reported
Obesity; Off Label Use;	Triamcinolone Hexacetonide			S	Unknown			Not Reported
Polyarthritis; Psoriasis;								
Red Blood Cell								
Sedimentation Rate								
Increased; Septic Shock;								
Synovitis; Vomiting								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851809	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS- 2020-AMRX-01271			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product	Hydroxychloroquine Sulfate			S	Unknown	Unk		Amneal
Substitution Issue								

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02-Jun-2020	17851835	EXPEDITED (15-DAY)		OT	CA-ROCHE-2609717		56 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pulmonary Fibrosis	Rituximab			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Orencia			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851836	EXPEDITED (15-DAY)		HO	CA-ROCHE-2605493		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; C- Reactive Protein Increased; Condition Aggravated; Contraindicated Product Administered; Disability; Drug Ineffective; Fall; Fatigue; Femur Fracture; Haematocrit Decreased; Haemoglobin Decreased; Impaired Healing; Joint Swelling; Multiple Fractures; Musculoskeletal Pain; Osteoporosis; Pain; Pain In Extremity; Peripheral Swelling; Rash; Red Blood Cell Count Decreased; Red Blood Cell Sedimentation Rate Abnormal; Synovitis	Actemra			S	Unknown			Not Reported	
	Adalimumab			S	Subcutaneous			Not Reported	
	Arava			S	Unknown			Not Reported	
	Atenolol			S	Unknown			Not Reported	
	Celecoxib			S	Unknown			Not Reported	
	Co Atenolol			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Etanercept			S	Unknown			Not Reported	
	Ferrous Fumarate			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Naprosyn [Naproxen]			S	Unknown			Not Reported	
	Naproxen Sodium			S	Unknown			Not Reported	

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Orencia	S	Intravenous (not otherwise specified)	Not Reported
Palafer	S	Unknown	Not Reported
Palafer Cf	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Xeljanz	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17851958	EXPEDITED (15-DAY)		OT	CA-ROCHE-2606524		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Alopecia; Condition Aggravated; Drug Ineffective; Drug Intolerance; Fatigue; Glossodynia; Hand Deformity; Hip Arthroplasty; Knee Arthroplasty; Pain; Pemphigus; Swelling; Systemic Lupus Erythematosis	Actemra			S	Unknown			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Arava			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Cimzia			S	Subcutaneous	Single-Use Prefilled Syringe		Not Reported
	Desoximetasone			S	Oral			Not Reported
	Enbrel			S	Subcutaneous			Not Reported
	Folic Acid			S	Unknown			Not Reported
	Fosamax			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Orencia			S	Subcutaneous			Not Reported

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	Phthalylsulfathiazole	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17852095	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-043010		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Ineffective; Drug Intolerance; Synovitis; Throat Tightness	Orencia			S	Unknown			Bristol Myers Squibb	
	Actemra			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Xeljanz			S	Oral	5 Milligram (2 In Every 1 Day)		Not Reported	
	Supeudol			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17852176	EXPEDITED (15-DAY)		DE, HO	ES-ROCHE-2612707		70 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Pneumonia Escherichia;	Hydroxychloroquine			S	Oral	400 Mg Dia		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	

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Ventricular Tachycardia	Tocilizumab	S						Not Reported
	Azitromicina	S	Intravenous (not otherwise specified)	500 Mg Dia				Not Reported
	Azitromicina	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17852203	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3426275-00		63 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic; Long Qt Syndrome	Kaletra 200/50			S	Oral				Not Reported
	Dolquine			S	Oral				Not Reported