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

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[CHLOROQUINE,CHLOROQUINE HYDROCHLORIDE,CHLOROQUINE PHOSPHATE,CHLOROQUINE SALICYLATE,CHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	01-Feb-2020	To:	09-Jun-2020
MedDRA® Version* :	23.0			
Total Cases**:	117			
Number of Pages:	52			

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.

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

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

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2020	15592728	EXPEDITED (15-DAY)		OT	ZA-SAKK-2018SA304134AA			Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Osteoarthritis; Tuberculin Test Positive; White Blood Cell Count Decreased	Arava			S	Unknown			Sanofi
	Methotrexate			S		Unk		Not Reported
	Chloroquine Sulfate			S		Unk		Sanofi
	Sulfasalazine			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Feb-2020	17420980	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020064178		32 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alanine Aminotransferase Increased; Anxiety Disorder; C-Reactive Protein Increased; Drug Ineffective; Fibromyalgia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Major Depression; Rheumatoid Arthritis; Sleep Apnoea Syndrome	Methotrexate			S		25 Mg, Unk		Pfizer
	Salazopyrin			S		2 G, Unk		Pfizer
	Chloroquine			S		200 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17423522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549981			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Synovitis	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

Chloroquine		S	Unknown		Not Reported
Acetaminophen		C	Unknown		Not Reported
Atorvastatin		C	Unknown		Not Reported
Enbrel		C			Not Reported
Methotrexate		C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2020	17424164	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184277		31 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Crying; Drug Ineffective; Joint Swelling	Leflunomide			S	Unknown			Barr
	Methotrexate			S	Unknown			Barr
	Chloroquine			S	Unknown			Not Reported
	Amitriptyline			C		150 Milligram Daily;		Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen			C				Not Reported
	Folate			C				Not Reported
	Pariet			C		40 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Feb-2020	15156214	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA183651			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Anxiety; Cachexia; Depression; Drug Intolerance; Job Dissatisfaction; Weight Decreased	Arava			S	Unknown	Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17413694	EXPEDITED (15-DAY)		OT	PHHY2019SE002330		68 YR	Female	SWE

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

Anxiety; Decreased Vibratory Sense; Dizziness; Drug Interaction; Erythema; Nerve Degeneration; Neuropathy Peripheral; Pain In Extremity; Peripheral Swelling; Polyneuropathy; Syncope; Systemic Lupus Erythematosus; Toxicity To Various Agents; Tremor	Ciprofloxacin Hydrochloride	S	Unknown	500 Mg, Bid	Novartis
	Naproxen	S	Unknown	500 Mg, 2x/Day (Bid Was Continued)	Not Reported
	Indometacin	S	Unknown	Unk	Not Reported
	Chloroquine	S	Unknown	250 Mg, Daily (More Than Five Years)	Not Reported
	Chloroquine	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Feb-2020	17439060	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA036863		29 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthropathy; Impaired Work Ability; Leukopenia; Nodule; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S		200 Mg		Sanofi
	Arava			S		20 Mg		Sanofi
	Methotrexate Sodium			C		20 Mg		Not Reported
	Arcoxia			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2020	17376191	EXPEDITED (15-DAY)		OT	NG-BAUSCH-BL-2020-003411		30 YR	Female	NGA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dystonia	Metronidazole			S	Intravenous (not otherwise specified)	Seven-Day Course Post-Operatively		Not Reported
	Metronidazole			S	Oral			Not Reported
	Chloroquine Phosphate			S	Oral	Once, On The Sixth Day Post Operatively		Not Reported
	Ampicillin			C	Oral	Postoperatively		Not Reported
	Benylin			C		Before Chloroquine Administration		Not Reported

	Acetaminophen	C	2 Tablets Prn		Not Reported
	Folic Acid	C			Not Reported
	Promethazine	C	Intramuscular		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	16231133	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110410			Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Drug Ineffective; Drug Ineffective; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Oral	400 Mg, Qd		Sanofi
	Methotrexate			S		25 Mg, Qw		Not Reported
	Methotrexate			S	Oral	10 Mg, Qw		Not Reported
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Prednisone			C	Oral	7 Mg, Qd		Not Reported
	Etanercept			C		50 Mg, Qw		Not Reported
	Cosentyx			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Mar-2020	16513224	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019278913		56 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Quality Of Life; Impaired Work Ability; Rheumatoid Arthritis	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
	Chloroquine			S		200 Mg, Daily		Not Reported
	Arava			S		20 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Mar-2020	17521544	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020103363		50 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diverticulum; Osteoarthritis;	Salazopyrin En			S		1 G, 2x/Day		Pfizer

Seronegative Arthritis	Nivaquine [Chloroquine]	S		200 Mg, Daily	Not Reported
	Arava	S		10 Mg, Weekly	Not Reported
	Folic Acid	C		5 Mg, Daily	Not Reported
	Arcoxia	C		90 Mg, Alternate Day	Not Reported
	Prednisone	C		10 Mg, 4x Per Week	Not Reported
	Tramacet	C		I/8 Hourly Prn	Not Reported
	Dormonoct	C		I/ Nocte Prn	Not Reported
	Lyrica	C		75-150 Mg, Daily Prn	Not Reported
	Cortisone	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Mar-2020	16971400	NON-EXPEDITED		OT	ZA-AMGEN-ZAFSP2018039633		61 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malignant Melanoma; Off Label Use; Upper Respiratory Tract Infection	Enbrel			S	Unknown	25 Milligram, Every 2 Weeks		Amgen
	Abitrexate			S	Subcutaneous	15 Milligram, Unk		Not Reported
	Plasmoquine			S	Unknown	200 Milligram 3/Week		Not Reported

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

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

Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Methotrexate Sodium	S	Subcutaneous	20 Mg	Not Reported
Methotrexate Sodium	S	Oral	20 Mg	Not Reported
Cyclosporine	S	Unknown		Novartis
Rituximab	S	Intravenous (not otherwise specified)		Not Reported
Humira	S	Subcutaneous		Not Reported
Chloroquine	S	Subcutaneous		Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Mg/Kg	Not Reported
Actemra	S	Intravenous (not otherwise specified)	8 Unk	Not Reported
Apo-Leflunomide	S	Oral		Not Reported
Enbrel	S	Subcutaneous	50 Mg, Qw	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Orencia	S	Subcutaneous	125 Mg	Not Reported
Plaquenil	S	Unknown		Not Reported
Remicade	S	Intravenous (not otherwise specified)	3 Mg	Not Reported
Rituxan	S	Intravenous (not otherwise specified)		Not Reported
Sulfasalazine	S	Oral		Not Reported
Xeljanz	C	Oral	5 Mg, Bid	Not Reported
Xeljanz Xr	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2020	17546843	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202541		60 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cataract; Off Label Use	Methotrexate			S	Subcutaneous			Barr

	Chloroquine		S	Unknown	Not Reported

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Methotrexate			S	Unknown			Barr
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17548310	EXPEDITED (15-DAY)		DS	CN-ABBVIE-20K-035-3317442-00		82 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Hepatocellular Injury; Off Label Use; Therapeutic Response Unexpected; Total Bile Acids Increased	Aluvia 200/50			S	Oral			Not Reported
	Aluvia 200/50			S				Not Reported
	Rosuvastatin Calcium			S	Oral			Not Reported
	Chloroquine Phosphate			S	Oral			Not Reported
	Chloroquine Phosphate			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2020	17553377	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309388		57 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hot Flush; Hyperhidrosis; Incorrect Drug Administration Rate; Infusion Related Reaction; Insomnia; Mucous Stools; Off Label Use; Pain;	Remicade			S	Intravenous (not otherwise specified)	Last Infusion: 04-Mar-2020		Not Reported
	Remicade			S				Not Reported
	Chloroquine			S	Unknown			Not Reported

Systemic Lupus Erythematosus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	14035262	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017422601		66 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Prostate Cancer	Methotrexate Sodium			S		30 Mg, Weekly		Pfizer
	Arava			S		20 Mg, Daily		Not Reported
	Chloroquine			S	Oral	200 Mg, Daily		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560170	EXPEDITED (15-DAY)		DS, HO	NVSC2020CN074307		82 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Coronavirus Infection; Decreased Appetite; Hepatocellular Injury; Total Bile Acids Increased	Rosuvastatin Calcium			S	Oral	1 Df, Qd		Novartis
	Lopinavir,Ritonavir			S	Oral	2 Df, Bid		Not Reported
	Chloroquine Phosphate			S	Oral	2 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Mar-2020	17560770	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA065892		38 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Arava			S	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Sanofi
	Sulfasalazine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2020	13850822	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2016GSK044952			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Alopecia; Arthralgia; Back Pain; Cerebrovascular Accident; Circumstance Or Information Capable Of Leading To Medication Error; Decreased Appetite; Dyspnoea; Fatigue; Foot Operation; Gait Disturbance; Hypersensitivity; Inappropriate Schedule Of Product Administration; Menorrhagia; Musculoskeletal Pain; Myalgia; Onychomycosis; Pain; Physical Examination Abnormal; Product Availability Issue; Product Dose Omission; Product Prescribing Issue; Pruritus; Somnolence; Speech Disorder; Systemic Lupus Erythematosus Rash; Tremor; Underdose; Vaginal Haemorrhage; Weight Decreased; Weight Increased	Belimumab			S		540 Mg, Unk		Glaxosmithkline
	Belimumab			S		540 Mg, Unk		Glaxosmithkline
	Marevan			S		2.5 Mg, Qd		Glaxosmithkline
	Fluconazole			S		Unk		Glaxosmithkline
	Chloroquine Phosphate			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Chloroquine			C		50 Mg, Unk		Not Reported
	Methotrexate			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2020	17598304	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA086753		58 YR	Male	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Apparent Death; C-Reactive Protein Increased; Deep Vein Thrombosis; Diverticulitis; Drug Ineffective;	Ilaris			S	Subcutaneous			Novartis
	Ilaris			S				Novartis
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S				Not Reported

Intentional Product Use Issue; Joint Swelling; Off Label Use; Pain; 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
	Arava	S	Unknown			Not Reported
	Arava	S				Not Reported
	Enbrel	S	Unknown			Not Reported
	Enbrel	S				Not Reported
	Humira	S	Subcutaneous	Solution		Not Reported
	Humira	S				Not Reported
	Chloroquine Phosphate	S	Unknown			Not Reported
	Chloroquine Phosphate	S				Not Reported
	Orencia	S	Intravenous (not otherwise specified)			Not Reported
	Orencia	S				Not Reported
	Remicade	S	Intravenous (not otherwise specified)	Powder For Solution		Not Reported
	Remicade	S				Not Reported
	Sodium Aurothiomalate	S	Unknown			Not Reported
	Sodium Aurothiomalate	S				Not Reported
	Sulfasalazine	S	Unknown			Not Reported
	Sulfasalazine	S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2020	15208555	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017517635		57 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Post Procedural Complication	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer
	Methotrexate			S		25 Mg, Unk		Pfizer
	Plasmoquine			S		1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2020	17610621	EXPEDITED (15-DAY)		OT	NL-ACCORD-177665		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Quetiapine			S		Tablet Mva, 300 Mg, 1 X Per Day 1 Piece		Not Reported
	Chloroquine			S		Tablet, 100 Mg, 2 X Per Dag 3 Stuks, 1e Dosis 6 Stuks		Not Reported
	Lithium			S		300 Mg, 1 X Per Dag 1 Piece		Not Reported
	Dalteparin			C		Injectievloeistof, 25.000 Ie/Ml (Eenheden Per Milliliter)		Not Reported
	Paracetamol			C		Infusion Liquid, 10 Mg / Ml (Milligrams Per Milliliter)		Not Reported
	Oxazepam			C		Tablet, 5 Mg (Milligram)		Not Reported
	Cefuroxime			C		Injection Liquid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17614974	EXPEDITED (15-DAY)		OT	NL-ASTRAZENECA-2020SE42678		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Quetiapine			S	Oral			Astrazeneca
	Chloroquine			S	Oral	Tablet, 100 Mg, 3 B.I.D., First Dose 6 Tablets		Not Reported
	Lithiumcarbonaat			S	Unknown			Not Reported
	Dalteparine			C	Unknown	1 Df, Injection Fluid, 25.000 Iu/Ml (Units Per Milliliter)		Not Reported
	Paracetamol			C	Unknown	1.0df Unknown		Not Reported
	Oxazepam			C	Unknown	5.0mg Unknown		Not Reported
	Cefuroxim			C		1.0df Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2020	17621574	DIRECT	Y	DE			32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Chloroquine			S	Oral			Not Reported
	Zejula			C				Not Reported
	Keytruda 100/4ml Vial Iv			C				Not Reported
	Celecoxib 400 Mg, Oral Capsule			C				Not Reported
	Afinitor 2.5 Mg, Tablet Oral			C				Not Reported
	Cyclophosphamide 25 Mg, Oral			C				Not Reported
	Capecitabine 500mg, Oral			C				Not Reported
	Chloroquine Ph, 250mg, Oral			C				Not Reported
	Procrit 20,000 Units/Ml Vial, Sq As Directed			C				Not Reported
	Neupogen 300 Mcg/ 0.5ml Syringe, Sq			C				Not Reported
	Venofer 200 Mg/10ml Vial Iv As Directed			C				Not Reported
	Chloroquine Ph 250 Mg, Daily			C				Not Reported
	Chloroquine Ph 250 Mg, Daily			C				Not Reported
	Venofer 200mg /10ml Vial Iv			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17620967	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020136716		24 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psoriasis; Rheumatoid Arthritis	Methotrexate			S		25 Mg, Weekly		Pfizer
	Chloroquine			S		200 Mg, Daily		Not Reported
	Cyclosporin A			S	Oral	75 Mg, 2x/Day		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2020	17623442	EXPEDITED (15-DAY)		DE, OT	BR-GLAXOSMITHKLINE-BR2017GSK141512		61 YR	Female	BRA

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

Arthralgia; Arthritis; Bronchitis; Death; Decreased Appetite; Dry Eye; Dysphagia; Gait Disturbance; Glossodynia; Hypoaesthesia; Inappropriate Schedule Of Product Administration; Joint Swelling; Lip Erythema; Oral Discomfort; Oropharyngeal Pain; Osteoarthritis; Pain In Extremity; Peripheral Coldness; Pneumonia; Product Dose Omission; Renal Disorder; Therapeutic Product Effect Decreased; Tongue Erythema; Underdose; Urinary Tract Infection; Visual Impairment; Weight Decreased; Weight Fluctuation; Wrong Product Administered; Wrong Technique In Product Usage Process	Benlysta	S		550 Mg, Unk	Glaxosmithkline
	Benlysta	S		500 Mg	Glaxosmithkline
	Chloroquine Phosphate	S		250 Mg, Unk	Glaxosmithkline
	Paracetamol	C		Unk	Glaxosmithkline
	Crestor	C		Unk	Glaxosmithkline
	Colecalciferol	C		Unk	Glaxosmithkline
	Methotrexate	C		Unk	Glaxosmithkline
	Mycophenolate	C		Unk	Glaxosmithkline
	Calcium	C		Unk	Glaxosmithkline
	Glucosamine	C		Unk	Glaxosmithkline
	Clopidogrel	C		Unk	Glaxosmithkline
	Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Prednisone	C		5 Mg, Unk	Not Reported
	Chondroitin	C		Unk	Not Reported
	Amytril	C		Unk	Not Reported
	Rivotril	C		Unk	Not Reported
	Endofolin	C		Unk	Not Reported
	Alginac	C		Unk(1000)	Not Reported
	Cilostazol	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Apr-2020	16462586	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA247056		70 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Benign Prostatic Hyperplasia; Hypertension; Platelet Count Abnormal; Prostate Cancer	Chloroquine (Salt Not Specified)			S		200 Mg		Sanofi
	Methotrexate			S		30 Mg		Not Reported
	Arava			S		20 Mg		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639061	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA071467			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rheumatoid Arthritis	Arava			S	Unknown	20 Mg		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg		Sanofi
	Methotrexate Sodium			S	Unknown	25 Mg		Not Reported
	Salazopyrin			S	Unknown	2 G		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Apr-2020	17639471	EXPEDITED (15-DAY)		OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001059			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaemia; Cardiomyopathy; Cutaneous Lupus Erythematosus; Neutropenia; Renal Failure; Retinal Injury; Thrombocytopenia; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	300 Milligram, Qd		Ipca
	Hydroxychloroquine			S	Unknown	Unk		Ipca

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17647436	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356481-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648543	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA075153		50 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Drug Reaction; Diverticulum; Osteoarthritis; Seronegative Arthritis	Arava			S		10 Mg, Qw		Sanofi
	Sulfasalazine			S		1 G, Bid		Not Reported
	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi
	Folic Acid			C				Not Reported
	Arcoxia			C				Not Reported
	Prednisone			C				Not Reported
	Tramacet			C				Not Reported
	Dormonoct			C				Not Reported
	Lyrica			C				Not Reported
	Cortisone			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2020	17648751	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3356478-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2020	15230238	NON-EXPEDITED		OT	ZA-AMGEN-ZAFSP2017181416		57 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Post Procedural Complication	Enbrel			S	Subcutaneous	25 Milligram, 2x/Week		Amgen
	Methotrexate			S	Unknown	25 Milligram, Unk		Not Reported
	Plasmoquine			S	Unknown	1 Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660080	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147592			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Myochrysine			S	Unknown			Not Reported
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660089	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147560			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate Sodium			S	Unknown			Pfizer
	Aralen [Chloroquine Sulfate]			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine			S	Unknown			Not Reported

	Sulfate]			
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17660569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020147922			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Off Label Use; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Aralen Hydrochloride			S		Unk		Not Reported
	Humira			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Myochrysine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine Phosphate]			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17662489	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1037190		73 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Potentiating Drug Interaction	Quetiapine			S		Tablet Mva, 300 Mg, 1 X Per Dag 1 Stuk		Not Reported
	Chloroquine			S		Tablet, 100 Mg, 2 X Per Dag 3 Stuks, 1e Dosis 6 Stuks		Mylan
	Lithiumcarbonaat			S		300 Mg, 1 X Per Dag 1 Stuk		Mylan
	Dalteparin			C		Injectievloeistof, 25.000 Ie/Ml (Eenheden Per Milliliter)		Mylan
	Paracetamol			C		Infusievloeistof, 10 Mg/Ml (Milligram Per Milliliter)		Mylan

	Oxazepam	C	Tablet, 5 Mg (Milligram)	Mylan
	Cefuroxim /00454601/	C	Injectievloeistof	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Apr-2020	17663224	EXPEDITED (15-DAY)		OT	FR-ADVANZ PHARMA-202003002823			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Angioedema	Hydroxychloroquine Sulfate (Authorized Generic),Plaquenil			S	Unknown	Unk		Concordia
	Nivaquine			S	Unknown	1 Dosage Form, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664171	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1698			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Deformity; Movement Disorder; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17664281	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1710			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Constipation; Polyarthritis; Product Use In	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported

Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Aralen	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Remicade	S	Unknown	Not Reported
	Sodium Aurothiomalate	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2020	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3362555-00			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	Humira			S	Subcutaneous			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Myochrysine			S	Intramuscular			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17668886	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1730			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective For Unapproved Indication; Musculoskeletal Stiffness; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Aralen Hydrochloride			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported

	Leflunomide	S	Unknown	Not Reported
	Myochrysine	S	Intramuscular	Not Reported
	Plaquenil	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671033	EXPEDITED (15-DAY)		DE	SI-AMNEAL PHARMACEUTICALS-2020-AMRX-01138		62 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Failure; Congestive Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2020	17671303	EXPEDITED (15-DAY)		OT	SI-AMNEAL PHARMACEUTICALS-2020-AMRX-01140		41 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Apr-2020	17677171	EXPEDITED (15-DAY)		HO	AU-VALIDUS PHARMACEUTICALS LLC-AU-2020VAL000308			Unknown	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression; Drug Ineffective; Off Label Use; Tachypnoea	Cefotaxime Sodium			S	Unknown	Unk		Validus
	Chloroquine			S	Oral	10 Mg/Kg, Qd		Not Reported
	Prednisolone			S	Oral	1 Mg/Kg, Qd		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	High Intravenous Dose		Not Reported
	Flucloxacillin			S	Unknown	Unk		Not Reported
	Tobramycin			S	Unknown	Unk		Not Reported

	Immunoglobulin /07494701/	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Hydrocortisone	C		Unk	Not Reported
	Albuterol /00139501/	C		Unk	Not Reported
	Ampicillin	C		Unk	Not Reported
	Erythromycin	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17678788	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3367101-00		34 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatocellular Injury	Kaletra 200/50			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Cloroquina			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2020	17679976	EXPEDITED (15-DAY)		HO, OT	DE-SANOFI-AVENTIS-2012SA019610		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Lip Disorder; Pigmentation Disorder; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Cyclophosphamide			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisone			S	Unknown	Unk Unk,Unk		Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown	Unk Unk,Unk		Sanofi
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk Unk,Unk		Not Reported
	Prednisolone			S	Unknown	Unk Unk,Unk		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi
	Leflunomide			S	Unknown	Unk Unk,Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17683654	EXPEDITED (15-DAY)		HO, OT	DE-IPCA LABORATORIES LIMITED-IPC-2020-DE-			Unknown	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective; Inflammation; Procalcitonin Increased	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Ipca
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Prednisolone			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17687792	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100987			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; 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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100832			Unknown	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2020	17688871	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100853			Unknown	CAN

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691669	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585066		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Eye Infection; Inflammation; Ocular Toxicity; Skin Discolouration; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vasculitic Rash	Rituxan			S	Intravenous drip			Not Reported
	Rituxan			S				Not Reported
	Mycophenolate Mofetil			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Actonel			C	Unknown			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported

	Losec [Omeprazole]	C	Unknown	Not Reported
	Medrol [Methylprednisolone]	C	Unknown	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17691901	EXPEDITED (15-DAY)		OT	SI-BAYER-2020-063855		54 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Chloroquine			S	Oral	250 Mg Experimental Therapy		Bayer
	Micardis			C				Not Reported
	Concor			C				Not Reported
	Aspirin Protect 100 Mg			C	Oral			Bayer
	Folkodin Alkaloid			C				Not Reported
	Lekadol C			C				Not Reported
	Sorvasta			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2020	17695429	EXPEDITED (15-DAY)		HO	DE-BAXTER-2020BAX008027		31 YR	Female	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epidermal Necrosis; Epidermal Necrosis; Lip Disorder; Lip Disorder; Pigmentation Disorder; Skin Lesion; Skin Lesion; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis; Toxic Epidermal Necrolysis	Endoxan Lyophilisat			S	Unknown			Baxter
	Leflunomide			S	Unknown			Not Reported
	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Prednisolone			S	Nasal			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17704891	EXPEDITED (15-DAY)		OT	CN-BAYER-2020-066076		47 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Resochin 250 Mg			S	Oral	0.5 G, Bid		Bayer
	Resochin 250 Mg			S				Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17027055	EXPEDITED (15-DAY)		OT	CA-SA-2019SA305783			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Rash	Nasacort			S	Oral	2 Mg		Sanofi
	Acetylsalicylic Acid			S	Unknown	80 Mg		Not Reported
	Calcium			S	Unknown	Unk, Unk		Sanofi
	Methotrexate			S	Oral	Unk		Not Reported
	Methotrexate			S	Subcutaneous	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	200 Ug		Not Reported
	Warfarin Sodium			S	Oral	2.0 Mg		Not Reported
	Chloroquine Diphosphate			S	Unknown	Unk Unk, Unk		Not Reported
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Azathioprine			S				Not Reported
	Varenicline Tartrate			S	Unknown			Not Reported
	Vitamin D [Colecalciferol]			C	Unknown	Unk, Unk		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Pantoprazole Magnesium			C		40 Mg, Qd		Not Reported
	Mycophenolate Mofetil			C		1000 Mg		Not Reported
	Mycophenolate Mofetil			C		500 Mg, Bid		Not Reported
	Folic Acid			C	Oral	5 Mg, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17672253	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411530		49 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative Arthritis; Treatment Failure	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cosentyx			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Hydroxychloroquine			S				Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Chloroquine Diphosphate			S	Unknown			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Orencia			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Erythromycin			C	Unknown			Not Reported
	Morphine			C	Topical			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2020	17620078	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3348741-00			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported
	Kaletra			S				Not Reported

	Azithromycin		S	Unknown	Not Reported
	Chloroquine		S	Unknown	Not Reported
	Ceftriaxone		C		Not Reported
	Tocilizumab		C		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Apr-2020	17687195	EXPEDITED (15-DAY)		OT	TH-ROCHE-2581494		38 YR	Male	THA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Off Label Use; Pneumonitis; Product Use In Unapproved Indication	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Tamiflu			S	Oral			Not Reported
	Chloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17727766	EXPEDITED (15-DAY)		OT	US-BAYER-2020-067458		63 YR	Female	AUS

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysstasia; Feeling Abnormal; Gait Inability; Malaise; Muscular Weakness; Nausea; Vertigo	Chloroquine			S		Unk		Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Apr-2020	17730609	EXPEDITED (15-DAY)		OT	FR-US-PROVELL PHARMACEUTICALS LLC-9071647			Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Back Pain; Dysstasia; Headache; Ill-Defined Disorder; Myalgia; Pain	Levothyrox			S				Not Reported
	Chloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-May-2020	17745411	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-019615			Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo
	Chloroquine			S	Unknown	Unk		Not Reported
	Kaletra			S	Oral	Unk		Not Reported
	Kaletra			S				Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Tocilizumab			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752542	EXPEDITED (15-DAY)		OT	SI-BAYER-2020-072342		71 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block First Degree; Electrocardiogram Qt Prolonged	Chloroquine			S	Oral	250 Mg Coated Tablets; 500mg At 12-Hour Intervals		Bayer
	Pantoprazol [Pantoprazole]			C				Not Reported
	Fentanyl			C				Not Reported
	Flucloxacilline [Flucloxacillin]			C				Not Reported
	Midazolam			C				Not Reported
	Dexmedetomidine			C				Not Reported
	Esmeron			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752580	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-072354		46 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Mania	Chloroquine			S				Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752587	EXPEDITED (15-DAY)		HO	NL-BAYER-2020-072388		68 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour; Sexual Inhibition	Chloroquine			S		300 Mg		Bayer
	Fraxiparine			C		Injection Liquid, 9500 Ie/Ml (Units Per Milliliter)		Not Reported
	Ceftriaxon			C		For Infusion, 2000 Mg (Milligrams)		Not Reported
	Amoxicilline [Amoxicillin Sodium]			C		Tablet, 500 Mg (Milligram)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752588	EXPEDITED (15-DAY)		HO	NL-BAYER-2020-072616		71 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Psychotic Disorder	Chloroquine			S		200 Mg, Q8hr		Bayer
	Fraxiparine			C		Injection Liquid, 9500 Ie/Ml (Units Per Milliliter)		Not Reported
	Insulin			C		Variable		Not Reported
	Entecavir			C		Unk		Not Reported
	Movicolon			C		Unk		Not Reported
	Ebilfumin			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752632	EXPEDITED (15-DAY)		HO	NL-BAYER-2020-073446		61 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epilepsy	Chloroquine			S		Unknown, Can Be Requested From Physician In Hospital		Bayer
	Ceftriaxon			C		Unknown, Can Be		Not Reported

	Azitromycine	C	Requested From Physician In Hospital Unknown, Can Be Requested From Physician In Hospital		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752638	EXPEDITED (15-DAY)		HO	ES-BAYER-2020-073621		34 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coronavirus Infection; Hepatitis	Chloroquine			S	Oral	155 Mg, Bid		Bayer
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Kaletra			S	Oral	2 Df, Bid		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2020	17752640	EXPEDITED (15-DAY)		HO, OT	NL-BAYER-2020-073405			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Delusion; Hypomania; Psychomotor Hyperactivity	Chloroquine			S		300 Mg, Bid		Bayer
	Chloroquine			S		600 Mg		Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	16344713	EXPEDITED (15-DAY)		OT	PHHY2019BR116537		80 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Abdominal Pain; Abdominal Pain Upper; Arthralgia; Blindness; Blood Pressure Decreased; Chest Pain; Cough; Diarrhoea;	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Adalimumab			S	Subcutaneous	1 Df, Unk (Once Every 15 Days)		Not Reported

Dizziness; Drug Ineffective; Drug Intolerance; Dysentery; Dyspepsia; Dysstasia; Feeling Abnormal; Gastrointestinal Infection; Generalised Oedema; Malaise; Metabolic Disorder; Nail Psoriasis; Palpitations; Peripheral Swelling; Pneumonia; Rhinitis; Sinusitis; Weight Decreased	Calcium	S	Oral	Unk, Qd	Not Reported
	Higroton	S	Oral	12.5 Mg, Qd	Not Reported
	Chloroquine	S	Oral		Not Reported
	Calcium	C	Oral	2 Df, Qd (After Lunch)	Not Reported
	Selozok	C	Oral	50 Mg, Qd	Not Reported
	Aspirin	C	Oral	1 Df, Qd	Not Reported
	Chlortalidone	C	Oral	12.5 Mg, Qd	Not Reported
	Prednisone	C	Oral	1 Df, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17728298	EXPEDITED (15-DAY)		DE	BR-BAYER-2020-072489		53 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Chloroquine			S				Bayer
	Azitromicina			S				Not Reported
	Tamiflu			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17754239	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-246200		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Nivaquine 100 Mg, Comprime Secable			S	Oral	2-3 Cp Par Jour		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756194	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-071746		74 YR	Male	NLD

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

Electrocardiogram Qt Prolonged; Nausea	Chloroquine	S	600 Mg, Once		Bayer
	Chloroquine	S	300 Mg, Bid		Bayer
	Rocuronium	C	Unk		Not Reported
	Captopril	C			Not Reported
	Propofol	C			Not Reported
	Insulin	C			Not Reported
	Macrogol	C			Not Reported
	Paracetamol	C			Not Reported
	Fentanyl	C			Not Reported
	Pantoprazol [Pantoprazole]	C			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756196	EXPEDITED (15-DAY)		HO	SI-BAYER-2020-072339		57 YR	Female	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Chloroquine			S	Oral	Experimental Therapy: 1g, Then 500 Mg/12h		Bayer
	Magnesium Sulfate			C				Not Reported
	Kventiax			C		In The Evening		Not Reported
	Helex			C		In The Evening		Not Reported
	Fraxiparine			C				Not Reported
	Lekadol			C				Not Reported
	Pantoprazole			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756200	EXPEDITED (15-DAY)		LT	SE-BAYER-2020-071748		43 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Blindness Transient; Diplopia; Heart Rate Increased; Muscle Spasms; Thunderclap Headache; Vomiting	Chloroquine			S		2 Tablets Morning, 2 Tablets Evening X 7 Days, 1000mg Per Day		Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756239	EXPEDITED (15-DAY)		HO, LT	NL-BAYER-2020-073397		68 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Depression Suicidal; Nausea; Off Label Use; Suicide Attempt	Chloroquine			S		Oplaat 600mg		Bayer
	Chloroquine			S		Then 2dd 3 Pieces Of 100 Mg		Bayer
	Amlodipine			C				Not Reported
	Fenprocoumon			C				Not Reported
	Paracetamol			C				Not Reported
	Oxazepam			C				Not Reported
	Amoxicilline [Amoxicillin]			C		500 Mg		Not Reported
	Cefuroxim [Cefuroxime]			C		500 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756248	EXPEDITED (15-DAY)		OT	IT-BAYER-2020-075494		54 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Gamma-Glutamyltransferase Increased	Chloroquine			S	Oral	500 Mg, Qd		Bayer
	Urbason [Methylprednisolone]			C	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-May-2020	17756641	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1045335		53 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Tachyarrhythmia	Zeclar			S	Unknown	1 Gram, Qd		Mylan
	Chloroquine			S	Oral	Unk		Mylan

	Cefotaxime		C	Unknown	2 Gram	Mylan
	Magnesium Sulphate /01097001/		C		Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-May-2020	17021154	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA309865			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Rheumatoid Arthritis; Vomiting	Arava			S	Unknown	20 Mg, Qd		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			C	Unknown	25 Mg, Qw		Not Reported
	Salazopyrin			C	Unknown	2 Mg, Qd		Not Reported
	Etanercept			C	Subcutaneous	50 Mg, Qw		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-May-2020	17767320	EXPEDITED (15-DAY)		HO, OT	NVSC2020SI123287		67 YR	Male	SVN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Body Temperature Increased; Cough; Electrocardiogram Qt Prolonged; Oropharyngeal Pain; Respiratory Failure; Respiratory Tract Infection; Tongue Discomfort; Tongue Dry	Amoksiklav			S	Intravenous (not otherwise specified)	1.2 G, Q8h		Novartis
	Chloroquine			S	Oral	1500 Mg (1g + 500 Mg), Q12h		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2020	13067806	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2016-15732		16 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Amaurosis; Anxiety; Areflexia; Condition Aggravated; Drug	Diphenhydramine			S	Unknown	Unk		Aurobindo
	Fluoxetine			S	Unknown	Unk		Aurobindo

Interaction; Facial Paralysis; Hallucination; Insomnia; Mydriasis; Paranoia; Toxic Encephalopathy; Toxicity To Various Agents	Olanzapine 2.5mg		S	Unknown	2.5 Mg, Unk	Aurobindo
	Olanzapine 2.5mg		S	Unknown	17.5 Mg, Unk	Aurobindo
	Risperidone		S	Unknown	Unk	Aurobindo
	Lorazepam		S	Unknown	Unk	Not Reported
	Benztropine Mesylate		S		Unk	Not Reported
	Clonazepam		S		Unk	Not Reported
	Chloroquine		S		250 Mg, Unk	Not Reported
	Azithromycin		C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17790293	EXPEDITED (15-DAY)		HO, OT	FR-IPCA LABORATORIES LIMITED-IPC-2020-FR-001539			Unknown	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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
	Clobetascol			C	Unknown	Unk, Qd		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Tramadol			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794573	EXPEDITED (15-DAY)		HO, LT	SE-BAYER-2020-076377		42 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Balance Disorder; Diarrhoea; Diplopia;	Chloroquine			S	Oral	2 Tablets Morning, 2 Tablets Evening X 7 Days		Bayer

Dizziness; Head Discomfort; Headache; Heart Rate Increased; Muscle Spasms; Venous Pressure Abnormal; Vision Blurred; Visual Field Defect; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-May-2020	17794930	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1235284		44 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Eye Infection; Inflammation; Ocular Toxicity; Skin Discolouration; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vasculitic Rash	Prednisone			S	Unknown			Actavis
	Azathioprine			S	Unknown	200 Milligram Daily;		Not Reported
	Chloroquine			S	Unknown	250 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S	Oral	3 Milligram Daily;		Teva
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Losec [Omeprazole]			C	Unknown			Not Reported
	Medrol [Methylprednisolone]			C	Unknown			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Risedronate Sodium			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-May-2020	17798528	EXPEDITED (15-DAY)		HO	FR-NATCO PHARMA-2020NAT00018		59 YR	Male	FRA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-May-2020	15986426	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2017GSK149224			Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anxiety; Asthma; Choking; Circumstance Or Information Capable Of Leading To Medication Error; Cough; Decreased Appetite; Decreased Immune Responsiveness; Depressed Mood; Depression; Dyspnoea; Emotional Distress; Eye Disorder; Fatigue; Fear; Haematoma; Hypotension; Inappropriate Schedule Of Product Administration; Influenza; Limb Injury; Lung Opacity; Malaise; Memory Impairment; Nasopharyngitis; Nephrolithiasis; Nervousness; Pain In Extremity; Patient	Benlysta			S		960 Mg, Unk		Glaxosmithkline
	Chloroquine			S		Unk		Not Reported
	Cortisone Acetate			C		Unk		Glaxosmithkline
	Seretide			C		Unk		Glaxosmithkline
	Velija			C		Unk (60)		Not Reported
	Deflazacort			C		6 Mg, Bid		Not Reported
	Alprazolam			C		Unk		Not Reported

Isolation; Poor Quality Sleep; Product Availability Issue; Product Dose Omission; Pulmonary Fibrosis; Retinal Disorder; Skin Discolouration; Social Problem; Stress; Systemic Lupus Erythematosus; Underdose; Varicose Vein; Vision Blurred; Visual Impairment; Weight Decreased; Weight Increased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17804897	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1236797		24 YR	Male	ESP

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-May-2020	17805239	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2020-IN-001602			Unknown	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abnormal Behaviour	Chloroquine			S	Unknown	600 Milligram, Qd		Ipca
	Chloroquine			S	Unknown	300 Milligram, Qd		Ipca
	Sulfadoxine Pyrimethamine			C	Unknown	1500 Mg/75 Mg		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810834	EXPEDITED (15-DAY)		HO	SE-BAYER-2020-090402		26 YR	Female	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Accidental Overdose; Electrocardiogram Qt Prolonged	Chloroquine			S	Oral	Unk		Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17810882	EXPEDITED (15-DAY)		OT	PL-ROCHE-2602576		30 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Interleukin Level Increased; Off Label Use	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Lopinavir;Ritonavir			S	Unknown			Not Reported
	Methylprednisolone			C				Not Reported
	Thyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812004	EXPEDITED (15-DAY)		OT	NVSC2020PH137092		66 YR	Male	PHL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Azithromycin			S	Unknown	250 Mg, Qd (Once Daily For 10 Days Ngt)		Novartis
	Chloroquine			S	Unknown	500 Mg, Bid (2x/Day For 10 Days)		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-May-2020	17812024	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2020169504		73 YR	Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abscess; Condition Aggravated; Sepsis; Treatment Failure	Salazopyrin			S		1 G, 2x/Day		Pfizer
	Methotrexate Sodium			S		25 Mg, Daily		Pfizer
	Plasmoquine			S		200 G, Daily		Not Reported
	Arava			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-May-2020	17817879	EXPEDITED (15-DAY)		OT	CN-BAYER-2020-090052		63 YR	Male	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Cytokine Storm; Dyspnoea; Hepatic Function Abnormal; Hypoxia; Leukopenia; Lymphocyte Count Increased; Oxygen Saturation Decreased; Po2 Decreased; Therapeutic Response Unexpected	Chloroquine			S	Oral	500 Mg, Bid, For 7 Days		Bayer
	Methylprednisolone			C	Intravenous (not otherwise specified)	80-40mg, For 5 Days		Not Reported
	Methylprednisolone			C				Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	8 Mg/Kg Immediately		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2020	17746062	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2020178143		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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			S	Oral	400 Mg, Daily, 2-3 Tablets		Not Reported

Sulfate] Per Day

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17765509	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2020-02071		59 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiotoxicity; Impaired Work Ability; Myopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin
	Hydroxychloroquine			S				Lupin
	Chloroquine			S	Unknown	Unk		Not Reported
	Chloroquine			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2020	17826076	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1050851			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arrhythmia; Off Label Use; Supraventricular Extrasystoles; Ventricular Tachycardia	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17757804	EXPEDITED (15-DAY)		OT	SE-BAYER-2020-071751		72 YR	Male	SWE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged	Chloroquine			S		Strength 250mg Dose 4x1in1, 2x2		Bayer
	Chloroquine			S		Daily Dose 1000 Mg		Bayer
	Atorvastatin Krka			C		20 Mg, Qd		Not Reported
	Alvedon			C		3 G, Qd, 1 G Film Coated Tablet		Not Reported
	Enalapril Comp			C		20 Mg/12.5 Mg Tablet		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17817899	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-092692		56 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Contraindicated Product Administered; Haemolytic Anaemia; Methaemoglobinaemia	Chloroquine			S		300 Mg, Bid		Bayer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-May-2020	17834177	EXPEDITED (15-DAY)		HO	IL-BAYER-2020-092694		84 YR	Female	ISR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Electrocardiogram Qt Prolonged; Torsade De Pointes	Chloroquine			S	Oral	500 Mg, Bid		Bayer
	Bisoprolol			C				Not Reported
	Letrozole			C				Not Reported
	Memantine			C				Not Reported
	Apixaban			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17830292	EXPEDITED (15-DAY)		OT	NVSC2020FR145080		59 YR	Male	FRA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17837429	EXPEDITED (15-DAY)		OT	NL-ALVOGEN-2020-ALVOGEN-108504		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Gastric Emptying	Fentanyl			S				Not Reported

	Chloroquine		S	Oplaaddosering Van 600 Mg Op 23-03	Not Reported
	Chloroquine		S	Daarna 2dd 300 Mg Van 24-03 T/M 28-03	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2020	17839236	EXPEDITED (15-DAY)		OT	NL-BIODELIVERY SCIENCES INTERNATIONAL-2020BDSI0363		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Gastric Emptying	Fentanyl Citrate			S	Unknown			Not Reported
	Chloroquine			S		Oplaaddosering Van 600 Mg Op 23-03		Not Reported
	Chloroquine			S		Daarna 2dd 300 Mg Van 24-03 T/M 28-03		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	14152913	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017467944		21 YR	Male	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cachexia; Drug Ineffective; Gastrooesophageal Reflux Disease; Hepatic Steatosis; Hypersensitivity	Methotrexate Sodium			S	Subcutaneous	30 Ug, Weekly		Pfizer
	Salazopyrin			S		1 G, Twice A Day		Pfizer
	Plasmaquine			S		200 Ug, Daily		Not Reported
	Arava			S		20 Ug, Daily		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Weekly		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17813347	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLABS-2020M1049414		35 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Kidney Injury; Acute Respiratory Distress	Everolimus			S		3 Milligram, Bid		Not Reported

Syndrome; Cough; Covid-19 Pneumonia; Diarrhoea; Drug Abuse; Drug Interaction; Dyspnoea; Headache; Hypoxia; Intentional Product Misuse; Interstitial Lung Disease; Lung Consolidation; Lymphopenia; Malaise; Metabolic Acidosis; Myalgia; Nasal Congestion; Nausea; Off Label Use; Pneumococcal Infection; Productive Cough; Pyrexia; Rales; Renal Failure; Renal Impairment; Respiratory Alkalosis; Respiratory Failure; Rhabdomyolysis; Rhinorrhoea; Tachypnoea; Toxicity To Various Agents; Tubulointerstitial Nephritis; Vomiting	Everolimus	S	Unknown	6 Milligram, Qd	Not Reported
	Everolimus	S	Unknown	3 Milligram, Qd	Not Reported
	Everolimus	S	Unknown	2 Milligram, Qd	Not Reported
	Everolimus	S	Unknown	4 Milligram, Qd	Not Reported
	Everolimus	S	Unknown	2 Milligram, Bid	Not Reported
	Prednisolone	S		7.5 Milligram, Qd	Not Reported
	Kaletra	S	Oral	2 Dosage Form, Qd (Unit Dose: 400/100 Mg)	Mylan
	Kaletra	S	Oral	Unit Dose: 400/100 Mg	Mylan
	Chloroquine	S	Oral	600 Milligram, Qd	Mylan
	Chloroquine	S	Oral	600 Milligram (Loading Dose)	Mylan
	Chloroquine	S	Oral	600 Milligram (Loading Dose)	Mylan
	Chloroquine	S	Oral	300 Milligram, Bid	Mylan
	Chloroquine	S	Oral	300 Milligram, Qd	Mylan
	Tramadol	C		Unk	Mylan
	Tramadol	C		Unk	Mylan
	Tramadol	C		Unk	Mylan
	Tramadol	C		Unk	Mylan
	Tramadol	C		Unk	Mylan
	Ceftriaxone	C		Unk	Mylan
	Acetaminophen	C		Unk	Mylan
	Acetaminophen	C		Unk	Mylan
	Acetaminophen	C		Unk	Mylan
	Acetaminophen	C		Unk	Mylan
	Acetaminophen	C		Unk	Mylan
	Cefuroxime	C	Intravenous (not otherwise specified)	Unk	Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17846646	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1052432		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Gastric Emptying	Fentanyl			S		Unk		Not Reported
	Chloroquine			S		Oplaaddosering Van 600 Mg Op 23-03		Mylan
	Chloroquine			S		Daarna 2dd 300 Mg Van 24-03 T/M 28-03.		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847238	EXPEDITED (15-DAY)		OT	NVSC2020US149060		49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Arthritis; Drug Interaction; Drug-Induced Liver Injury; Hepatic Enzyme Abnormal	Rifampicin			S	Unknown	Unk		Novartis
	Isoniazid			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Pyrazinamide			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	200 Mg, 4w		Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	30 Mg, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2020	17847737	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-099151		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Gastric Emptying	Chloroquine			S		600 Mg, Qd		Bayer
	Chloroquine			S		300 Mg, Bid		Bayer
	Fentanyl			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17848628	EXPEDITED (15-DAY)		HO	ES-ROCHE-2609780		34 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Condition Aggravated; Hepatitis; Hepatocellular Injury	Tocilizumab			S	Unknown	600 Mg Dia		Not Reported
	Cloroquina [Chloroquine]			S	Oral	155 Mg Cada 12 Horas		Not Reported
	Kaletra			S	Oral	2 U Cad 12 Horas		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jun-2020	17851718	EXPEDITED (15-DAY)		OT	PL-ABBVIE-20K-129-3426312-00		30 YR	Female	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intentional Product Use Issue; Interleukin Level Increased; Off Label Use	Lopinavir/Ritonavir			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methylprednisolone			C				Not Reported
	Thyroxine			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2020	17856344	EXPEDITED (15-DAY)		OT	NL-TEVA-2020-NL-1242872		64 YR	Male	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Impaired Gastric Emptying	Fentanyl			S	Unknown	Therapy End Date : Asked But Unknown		Cephalon
	Chloroquine			S	Unknown	600 Mg Loading Dose On 3/23, Therapy End Date : Asked But Unknown		Not Reported

	Chloroquine	S	600 Milligram Daily; Then 300 Mg Twice Daily From 24-03 To 28-03.		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17771128	EXPEDITED (15-DAY)		DS, LT	FR-MYLANLABS-2020M1045669		43 YR	Male	FRA

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17858935	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204764		64 YR	Female	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Interaction; Electrocardiogram Qt Prolonged; Protein C Decreased; Protein C Increased	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Quinacris			S	Other	500 Mg, 2x/Day		Not Reported
	Kaletra			S	Other	2 Df, 2x/Day		Not Reported
	Bromoprida			C	Intravenous (not otherwise specified)	30 Mg, 3x/Day		Not Reported
	Vancomicina [Vancomycin Hydrochloride]			C	Intravenous (not otherwise specified)	1 G, 2x/Day		Not Reported
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed		Not Reported
	Euthyrox			C	Other	50 Ug, 1x/Day		Not Reported
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Mg, As Needed		Not Reported
	Norepinefrina [Norepinephrine Bitartrate]			C	Intravenous (not	16 Mg, As Needed		Not Reported

			otherwise specified)		
	Ionclor	C	Other	20 Ml, 3x/Day	Not Reported
	Lasix [Furosemide]	C	Intravenous (not otherwise specified)	30 Mg, 3x/Day	Not Reported
	Meronem	C	Intravenous (not otherwise specified)	1 G, 3x/Day	Not Reported
	Muvinlax	C	Oral	14 G, 2x/Day	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Oral	20 Mg, 1x/Day	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, 2x/Day	Not Reported
	Hydroxychloroquine	C	Other	400 Mg, 2x/Day	Not Reported
	Simvastatin	C		10 Mg, 1x/Day	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17859334	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-248933		48 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Disease Progression	Methotrexate			S	Unknown	30 Milligram, Weekly		Sun
	Chloroquine			S	Unknown	150 Milligram 4 Times Per Week		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2020	17861385	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2020-FR-1241998		47 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Atrioventricular Block Complete; Bundle Branch Block; Conduction Disorder; Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia; Left Ventricular	Fenofibrate			S	Unknown			Actavis
	Hydroxychloroquine			S	Unknown	400mg Per Day 7.4 Mg/Kg/Day		Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown			Not Reported

Hypertrophy; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Weight Decreased	Clopidogrel	C	Unknown		Not Reported
	Ranitidine	C	Unknown		Not Reported
	Clobetasol	C	Unknown	1 Application/Day	Not Reported
	Tramadol/Paracetamol	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2020	17703460	EXPEDITED (15-DAY)		DS, LT, OT	FR-AUROBINDO-AUR-APL-2020-020222		43 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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 (2-3 Tsp Per Day)		Not Reported