

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[CHLOROQUINE,CHLOROQUINE HYDROCHLORIDE,CHLOROQUINE PHOSPHATE]			
Active Moiety:				
FDA Received Date:	From:	01-Mar-2020	To:	01-Oct-2020
MedDRA® Version* :	23.0			
Total Cases**:	204			
Number of Pages:	101			

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>
02-Mar-2020	16513224	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019278913		56 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Mar-2020	17521544	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020103363		50 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diverticulum; Osteoarthritis; Seronegative Arthritis	Salazopyrin En			S		1 G, 2x/Day		Pfizer	
	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		1/8 Hourly Prn		Not Reported	
	Dormonox			C		1/ Nocte Prn		Not Reported	
	Lyrica			C		75-150 Mg, Daily Prn		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>
13-Mar-2020	17536862	EXPEDITED (15-DAY)		OT	NVSC2020CA065750		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	Neoral			S	Subcutaneous			Novartis	

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Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	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

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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	17546843	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1202541		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>	
Cataract; Off Label Use	Methotrexate			S	Subcutaneous			Barr	
	Chloroquine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	Methotrexate			S	Unknown			Barr	
Aggravated; Diverticulitis;	Chloroquine Diphosphate			S	Unknown			Not Reported	
H1n1 Influenza; Hepatic	Belimumab			S	Unknown			Not Reported	
Enzyme Increased;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Hepatomegaly;									
Palpitations; Pneumonia;									
Renal Disorder; Tooth									
Extraction; Tooth 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>
17-Mar-2020	17548310	EXPEDITED (15-DAY)		DS	CN-ABBVIE-20K-035-3317442-00		82 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>	
Blood Bilirubin Increased;	Aluvia 200/50			S	Oral			Not Reported	
Hepatocellular Injury; Off	Aluvia 200/50			S				Not Reported	
Label Use; Therapeutic	Rosuvastatin Calcium			S	Oral			Not Reported	
Response Unexpected;	Chloroquine Phosphate			S	Oral			Not Reported	
Total Bile Acids Increased	Chloroquine Phosphate			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-Mar-2020	17553377	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200309388		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>	
Hot Flush; Hyperhidrosis; Incorrect Drug Administration Rate; Infusion Related Reaction; Insomnia; Mucous Stools; Off Label Use; Pain; Systemic Lupus Erythematosus	Remicade			S	Intravenous (not otherwise specified)	Last Infusion: 04-Mar-2020		Not Reported	
	Remicade		S				Not Reported		
	Chloroquine		S	Unknown		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	14035262	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017422601		66 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17560170	EXPEDITED (15-DAY)		DS, HO	NVSC2020CN074307		82 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>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17560770	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA065892		38 YR	Female	ZAF
<u>Preferred Term</u>	<u>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	Unknown			Sanofi	

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Methotrexate	S	Unknown	Not Reported
Chloroquine (Salt Not Specified)	S	Unknown	Sanofi
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	13850822	EXPEDITED (15-DAY)		HO, OT	BR- GLAXOSMITHKLINE- BR2016GSK044952			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; 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

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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	17598304	EXPEDITED (15-DAY)		HO, LT	NVSC2020CA086753		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; Intentional Product Use	Methotrexate			S	Unknown			Not Reported	
Issue; Joint Swelling; Off Label Use; Pain;	Methotrexate			S				Not Reported	
Pulmonary Embolism; Pulmonary Thrombosis;	Actemra			S	Unknown			Not Reported	
Red Blood Cell Sedimentation Rate	Actemra			S				Not Reported	
Increased; Renal Failure; Sepsis; Thrombosis	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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17610621	EXPEDITED (15-DAY)		OT	NL-ACCORD-177665		73 YR	Female	NLD

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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	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/MI (Eenheden Per Milliliter)		Not Reported
	Paracetamol			C		Infusion Liquid, 10 Mg / MI (Milligrams Per Milliliter)		Not Reported
	Oxazepam			C		Tablet, 5 Mg (Milligram)		Not Reported
	Cefuroxime			C		Injection Liquid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17614974	EXPEDITED (15-DAY)		OT	NL-ASTRAZENECA-2020SE42678		73 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>
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/MI (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

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Detailed Report

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02-Apr-2020	17621574	DIRECT	Y	DE			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>
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			C				Not Reported
	As Directed							
	Neupogen 300 Mcg/ 0.5ml			C				Not Reported
	Syringe, Sq							
	Venofer 200 Mg/10ml Vial Iv As			C				Not Reported
	Directed							
	Chloroquine Ph 250 Mg, Daily			C				Not Reported
	Chloroquine Ph 250 Mg, Daily			C				Not Reported
	Venofer 200mg /10ml Vial 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>
03-Apr-2020	17620967	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020136716		24 YR	Female	ZAF

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17623442	EXPEDITED (15-DAY)		DE, OT	BR-GLAXOSMITHKLINE-BR2017GSK141512		61 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>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	16462586	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA247056		70 YR	Male	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Benign Prostatic Hyperplasia;	Chloroquine (Salt Not Specified)			S		200 Mg		Sanofi
Hypertension; Platelet Count Abnormal; Prostate Cancer	Methotrexate			S		30 Mg		Not Reported
	Arava			S		20 Mg		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>
07-Apr-2020	17639061	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA071467			Female	ZAF
<u>Preferred Term</u>	<u>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	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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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
<u>Preferred Term</u>	<u>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>
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; Polyarthrits; 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	

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

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	17648543	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA075153		50 YR	Male	ZAF

<u>Preferred Term</u>	<u>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; 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
	Dormonox			C				Not Reported
	Lyrica			C				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>
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; 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 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	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; 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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17662489	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1037190		73 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>	
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/MI (Eenheden Per Milliliter)		Mylan	
	Paracetamol			C		Infusievloeistof, 10 Mg/MI (Milligram Per Milliliter)		Mylan	
	Oxazepam			C		Tablet, 5 Mg (Milligram)		Mylan	
	Cefuroxim /00454601/			C		Injectievloeistof		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>
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>
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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 PHARMA-TREX2020-1710			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; Polyarthritis; Product Use In Unapproved Indication; Skin Lesion; Treatment Failure; Uveitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Aralen			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	

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

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	17668362	EXPEDITED (15-DAY)		OT	CA-ABBVIE-20K-028-3362555-00			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>
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>
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; 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

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>
15-Apr-2020	17671033	EXPEDITED (15-DAY)		DE	SI-AMNEAL PHARMACEUTICALS- 2020-AMRX-01138		62 YR	Female	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>	
Cardiac Failure; Congestive Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17671303	EXPEDITED (15-DAY)		OT	SI-AMNEAL PHARMACEUTICALS- 2020-AMRX-01140		41 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>	
Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17677171	EXPEDITED (15-DAY)		HO	AU-VALIDUS PHARMACEUTICALS LLC-AU- 2020VAL000308			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>	
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	

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Albuterol /00139501/	C	Unk	Not Reported
Ampicillin	C	Unk	Not Reported
Erythromycin	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	17678788	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3367101-00		34 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; Hepatocellular Injury	Kaletra 200/50			S	Oral			Not Reported
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported
	Cloroquina			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	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 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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17683654	EXPEDITED (15-DAY)		HO, OT	DE-IPCA LABORATORIES LIMITED-IPC-2020-DE-001199			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>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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; Polyarthrits; 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	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>
Constipation; Polyarthrits; 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

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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	17691669	EXPEDITED (15-DAY)		OT	CA-ROCHE-2585066		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; 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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17691901	EXPEDITED (15-DAY)		OT	SI-BAYER-2020-063855		54 YR	Female	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	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	

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Sorvasta			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	Leflunomide			S	Unknown			Not Reported	
Disorder; Lip Disorder;	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported	
Pigmentation Disorder;	Chloroquine			S	Unknown			Not Reported	
Skin Lesion; Skin Lesion;	Prednisone			S	Unknown			Not Reported	
Stevens-Johnson	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
Syndrome; Toxic	Prednisolone			S	Nasal			Not Reported	
Epidermal Necrolysis;									
Toxic Epidermal									
Necrolysis; Toxic									
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>
24-Apr-2020	17704891	EXPEDITED (15-DAY)		OT	CN-BAYER-2020-066076		47 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>	
Electrocardiogram Qt	Resochin 250 Mg			S	Oral	0.5 G, Bid		Bayer	
Prolonged; Off Label Use;	Resochin 250 Mg			S				Bayer	
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>
27-Apr-2020	17027055	EXPEDITED (15-DAY)		OT	CA-SA-2019SA305783			Female	CAN
<u>Preferred Term</u>	<u>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	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	

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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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17620078	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3348741-00			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; 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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17687195	EXPEDITED (15-DAY)		OT	TH-ROCHE-2581494		38 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>
Off Label Use; Pneumonitis; Product Use In Unapproved Indication	Actemra			S	Intravenous (not otherwise specified)			Not Reported

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

Tamiflu	S	Oral	Not Reported
Chloroquine	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>
30-Apr-2020	17727766	EXPEDITED (15-DAY)		OT	US-BAYER-2020-067458		63 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>
Dysstasia; Feeling Abnormal; Gait Inability; Malaise; Muscular Weakness; Nausea; Vertigo	Chloroquine			S		Unk		Bayer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17730609	EXPEDITED (15-DAY)		OT	FR-US-PROVELL PHARMACEUTICALS LLC-9071647			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>
Adverse Event; Back Pain; Dysstasia; Headache; Ill-Defined Disorder; Myalgia; Pain	Levothyrox			S				Not Reported
	Chloroquine			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	17745411	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-019615			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; 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

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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>
06-May-2020	17752542	EXPEDITED (15-DAY)		OT	SI-BAYER-2020-072342		71 YR	Female	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>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17752580	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-072354		46 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>	
Mania	Chloroquine			S				Bayer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17752587	EXPEDITED (15-DAY)		HO	NL-BAYER-2020-072388		68 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>	
Abnormal Behaviour; Sexual Inhibition	Chloroquine			S		300 Mg		Bayer	
	Fraxiparine			C		Injection Liquid, 9500 Ie/MI (Units Per Milliliter)		Not Reported	
	Ceftriaxon			C		For Infusion, 2000 Mg (Milligrams)		Not Reported	
	Amoxicilline [Amoxicillin Sodium]			C		Tablet, 500 Mg (Milligram)		Not Reported	

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06-May-2020	17752588	EXPEDITED (15-DAY)		HO	NL-BAYER-2020-072616		71 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>	
Psychotic Disorder	Chloroquine			S		200 Mg, Q8hr		Bayer	
	Fraxiparine			C		Injection Liquid, 9500 Ie/MI (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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17752632	EXPEDITED (15-DAY)		HO	NL-BAYER-2020-073446		61 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>	
Epilepsy	Chloroquine			S		Unknown, Can Be Requested From Physician In Hospital		Bayer	
	Ceftriaxon			C		Unknown, Can Be Requested From Physician In Hospital		Not Reported	
	Azitromycine			C		Unknown, Can Be Requested From Physician In Hospital		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17752638	EXPEDITED (15-DAY)		HO	ES-BAYER-2020-073621		34 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>	
Coronavirus Infection; Hepatitis	Chloroquine			S	Oral	155 Mg, Bid		Bayer	

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Tocilizumab		S	Intravenous (not otherwise specified)	600 Mg, Qd	Not Reported				
Kaletra		S	Oral	2 Df, 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	17752640	EXPEDITED (15-DAY)		HO, OT	NL-BAYER-2020-073405			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>	
Delusion; Hypomania; Psychomotor Hyperactivity	Chloroquine			S		300 Mg, Bid		Bayer	
	Chloroquine			S		600 Mg		Bayer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17728298	EXPEDITED (15-DAY)		DE	BR-BAYER-2020-072489		53 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>	
Death	Chloroquine			S				Bayer	
	Azithromycin			S				Not Reported	
	Tamiflu			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	17756194	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-071746		74 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>	
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	

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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	17756196	EXPEDITED (15-DAY)		HO	SI-BAYER-2020-072339		57 YR	Female	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	Chloroquine			S	Oral	Experimental Therapy: 1g, Then 500 Mg/12h		Bayer	
	Magnesium Sulfate 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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17756200	EXPEDITED (15-DAY)		LT	SE-BAYER-2020-071748		43 YR	Male	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; 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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17756239	EXPEDITED (15-DAY)		HO, LT	NL-BAYER-2020-073397		68 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>	
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	

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		Oxazepam		C					Not Reported
		Amoxicilline [Amoxicillin]		C		500 Mg			Not Reported
		Cefuroxim [Cefuroxime]		C		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>
07-May-2020	17756248	EXPEDITED (15-DAY)		OT	IT-BAYER-2020-075494		54 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-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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17756641	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2020M1045335		53 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>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17021154	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA309865			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<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; 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	

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Salazopyrin	C	Unknown	2 Mg, Qd	Not Reported
Etanercept	C	Subcutaneous	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>
11-May-2020	17767320	EXPEDITED (15-DAY)		HO, OT	NVSC2020SI123287		67 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>
Body Temperature Increased; Cough;	Amoksiklav			S	Intravenous (not otherwise specified)	1.2 G, Q8h		Novartis
Electrocardiogram Qt Prolonged; Oropharyngeal Pain; Respiratory Failure; Respiratory Tract Infection; Tongue Discomfort; Tongue Dry	Chloroquine			S	Oral	1500 Mg (1g + 500 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>
14-May-2020	13067806	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2016-15732		16 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>
Amaurosis; Anxiety; Areflexia; Condition Aggravated; Drug Interaction; Facial Paralysis; Hallucination; Insomnia; Mydriasis; Paranoia; Toxic Encephalopathy; Toxicity To Various Agents	Diphenhydramine			S	Unknown	Unk		Aurobindo
	Fluoxetine			S	Unknown	Unk		Aurobindo
	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
	Benzotropine Mesylate			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported
	Chloroquine			S		250 Mg, Unk		Not Reported
	Azithromycin			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	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17794573	EXPEDITED (15-DAY)		HO, LT	SE-BAYER-2020- 076377		42 YR	Male	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; Diarrhoea; Diplopia; Dizziness; Head Discomfort; Headache; Heart Rate Increased; Muscle Spasms; Venous Pressure Abnormal; Vision Blurred; Visual Field Defect; Vomiting	Chloroquine			S	Oral	2 Tablets Morning, 2 Tablets Evening X 7 Days		Bayer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17794930	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1235284		44 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; 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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	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

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Paracetamol/Tramadol			C	Unknown	If 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>
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	17805239	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2020-IN-001602			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>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17810834	EXPEDITED (15-DAY)		HO	SE-BAYER-2020-090402		26 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>	
Accidental Overdose; Electrocardiogram Qt Prolonged	Chloroquine			S	Oral	Unk		Bayer	

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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	17812004	EXPEDITED (15-DAY)		OT	NVSC2020PH137092		66 YR	Male	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	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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	18271912	DIRECT					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>	
Product Use Issue	Clarithromycin			S			9 DAY	Not Reported	
	Chloroquine			S			6 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	17817879	EXPEDITED (15-DAY)		OT	CN-BAYER-2020-090052		63 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>	
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	

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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	17826076	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1050851			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>	
Arrhythmia; Off Label Use; Supraventricular Extrasystoles; Ventricular Tachycardia	Lopinavir/Ritonavir			S	Unknown	Unk		Not Reported	
	Chloroquine			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>
28-May-2020	17757804	EXPEDITED (15-DAY)		OT	SE-BAYER-2020-071751		72 YR	Male	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>	
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	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17817899	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-092692		56 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>	
Contraindicated Product Administered; Haemolytic Anaemia; Methaemoglobinaemia	Chloroquine			S		300 Mg, Bid		Bayer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17834177	EXPEDITED (15-DAY)		HO	IL-BAYER-2020-092694		84 YR	Female	ISR

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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; 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		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17837429	EXPEDITED (15-DAY)		OT	NL-ALVOGEN-2020-ALVOGEN-108504		64 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>	
Impaired Gastric Emptying	Fentanyl			S		Oplaaddosering Van 600 Mg Op 23-03		Not Reported	
	Chloroquine			S				Not Reported	
	Chloroquine			S		Daarna 2dd 300 Mg Van 24-03 T/M 28-03		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17839236	EXPEDITED (15-DAY)		OT	NL-BIODELIVERY SCIENCES INTERNATIONAL-2020BDSI0363		64 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>	
Impaired Gastric Emptying	Fentanyl Citrate			S	Unknown	Oplaaddosering Van 600 Mg Op 23-03		Not Reported	
	Chloroquine			S				Not Reported	
	Chloroquine			S		Daarna 2dd 300 Mg Van 24-03 T/M 28-03		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17846646	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1052432		64 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>	

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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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17847737	EXPEDITED (15-DAY)		OT	NL-BAYER-2020-099151		64 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>	
Impaired Gastric Emptying	Chloroquine			S		600 Mg, Qd		Bayer	
	Chloroquine			S		300 Mg, Bid		Bayer	
	Fentanyl			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	17848628	EXPEDITED (15-DAY)		HO	ES-ROCHE-2609780		34 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; 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	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17851718	EXPEDITED (15-DAY)		OT	PL-ABBVIE-20K-129-3426312-00		30 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>	
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	

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	Chloroquine	S	Unknown	Not Reported
	Chloroquine	S	Unknown	Not Reported
	Methylprednisolone	C		Not Reported
	Thyroxine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17856344	EXPEDITED (15-DAY)		OT	NL-TEVA-2020-NL-1242872		64 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>	
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	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17858935	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204764		64 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>	
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	

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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 otherwise specified)	16 Mg, As Needed	Not Reported
Ionclor	C	Other	20 MI, 3x/Day	Not Reported
Lasix [Furosemide]	C	Intravenous (not otherwise specified)	30 Mg, 3x/Day	Not Reported
Meronom	C	Intravenous (not otherwise specified)	1 G, 3x/Day	Not Reported
Muvinalax	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17859334	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-248933		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>
Disease Progression	Methotrexate			S	Unknown	30 Milligram, Weekly		Sun
	Chloroquine			S	Unknown	150 Milligram 4 Times Per 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>
08-Jun-2020	17703460	EXPEDITED (15-DAY)		DS, 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	

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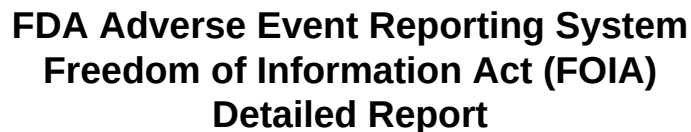
Nivaquine	S	Oral	200 Milligram, Once A Day (2-3 Cp Per Day)	Not Reported
Plaquenil	S	Oral	400 Milligram, Once A Day (2-3 Tsp Per Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17875718	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP011809			Female	CAN

<u>Preferred Term</u>	<u>Product</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; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Rash; Retinal Toxicity; Vomiting	Azathioprine			S	Unknown	Unk		Apotex
	Methotrexate			S	Oral	Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Novartis
	Methotrexate			S	Subcutaneous	25 Mg, Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Varenicline			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Asaphen			C	Unknown	80 Mg, Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Nasacort			C	Unknown	55 Mg, Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	40 Mg, Qd		Not Reported
	Prednisone			C	Unknown	10 Mg, Qd		Not Reported
	Synthroid			C	Unknown	220 Mg, Unk		Not Reported
	Warfarin Sodium			C	Oral	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>
10-Jun-2020	15643370	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA- 978063		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; Arthritis; C-Reactive Protein Increased; Drug	Azathioprine			S	Unknown	200 Milligram Daily;		Not Reported
	Chloroquine			S	Unknown	250 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>
11-Jun-2020	17883837	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-246272		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>	
Atrioventricular Block Complete; Cardiotoxicity; Ischaemic Cardiomyopathy; Muscle Atrophy; Musculoskeletal Toxicity; Syncope	Hydroxychloroquine			S	Unknown	400 Milligram, Daily		Sun	
	Chloroquine			S	Unknown	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>
12-Jun-2020	17847238	EXPEDITED (15-DAY)		OT	NVSC2020US149060		49 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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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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17889083	EXPEDITED (15-DAY)		HO, OT	CO-ACCORD-184888		37 YR	Male	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>
Candida Infection; Device Related Infection	Methotrexate			S				Accord
	Chloroquine			S				Not Reported
	Leflunomide			S				Not Reported
	Prednisolone			S		One Drop Of Prednisolone Every 6 Hours		Not Reported
	Meropenem			S				Not Reported
	Vancomycin			S				Not Reported
	Daptomycin			S				Not Reported
	Cefepime			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-Jun-2020	17889900	EXPEDITED (15-DAY)		HO, OT	CO-AXELLIA-003199		37 YR	Male	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>
Candida Infection; Device Related Infection	Vancomycin			S				Not Reported
	Daptomycin			S				Not Reported
	Cefepime			S				Not Reported
	Meropenem			S				Not Reported
	Prednisolone			S		One Drop Of Prednisolone Every 6 Hours		Not Reported
	Leflunomide			S				Not Reported
	Chloroquine			S				Not Reported

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Methotrexate		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-Jun-2020	16344713	EXPEDITED (15-DAY)		OT	PHHY2019BR116537		80 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>	
Abdominal Discomfort;	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis	
Abdominal Pain;	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis	
Abdominal Pain Upper;	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis	
Arthralgia; Blindness;	Adalimumab			S	Subcutaneous	1 Df, Unk (Once Every 15 Days)		Not Reported	
Blood Pressure Decreased; Chest Pain;	Calcium			S	Oral	Unk, Qd		Not Reported	
Cough; Diarrhoea;	Higroton			S	Oral	12.5 Mg, Qd		Not Reported	
Dizziness; Drug Ineffective; Drug Intolerance; Dysentery;	Chloroquine			S	Oral	Unk		Not Reported	
Dyspepsia; Dysstasia;	Calcium			C	Oral	2 Df, Qd (After Lunch)		Not Reported	
Feeling Abnormal;	Selozok			C	Oral	50 Mg, Qd		Not Reported	
Gastrointestinal Infection;	Aspirin			C	Oral	1 Df, Qd		Not Reported	
Generalised Oedema;	Chlortalidone			C	Oral	12.5 Mg, Qd		Not Reported	
Malaise; Metabolic Disorder; Nail Psoriasis;	Prednisone			C	Oral	1 Df, Qd		Not Reported	
Palpitations; Peripheral Swelling; Pneumonia;									
Rhinitis; Sinusitis; 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>
13-Jun-2020	17862681	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-026891		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>	
Atrioventricular Block Complete; Bundle Branch Block; Conduction Disorder; Decreased Appetite; Drug Ineffective;	Fenofibrate			S	Unknown	100 Milligram, Daily		Aurobindo	
Dysphagia; Dysphonia;	Chloroquine			S	Unknown	200 Milligram, Once A Day		Not Reported	
Left Ventricular	Hydroxychloroquine			S	Unknown	400 Milligram, Once A Day (400mg Per Day 7.4 Mg/Kg/Day)		Not Reported	
	Ranitidine			C	Unknown	300 Milligram, Once A Day		Not Reported	

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Hypertrophy; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Weight Decreased	Clopidogrel	C	Unknown	75 Milligram, Once A Day	Not Reported
	Acetylsalicylic Acid	C	Unknown	75 Milligram, Once A Day	Not Reported
	Paracetamol; Tramadol	C	Unknown	Unk	Not Reported
	Aspirin Aluminium	C	Unknown	Unk	Not Reported
	Clobetasol	C	Unknown	1 Application/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-Jun-2020	17907133	EXPEDITED (15-DAY)		OT	CA-ROCHE-2621114			Female	CAN

<u>Preferred Term</u>	<u>Product</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; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Rash; Retinal Toxicity; Vomiting	Mycophenolate Mofetil			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Varenicline Tartrate			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Asaphen			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Nasacort			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Warfarin 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>
17-Jun-2020	17908796	EXPEDITED (15-DAY)		OT	GB-BAYER-2020-110054		41 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>	
Cardiac Murmur	Chloroquine			S		On Same Day.		Bayer	

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	Multivitamins [Vitamins Nos]	C	Not Reported
	Ferrous Fumarate	C	Not Reported
	Zinc Sulphate	C	Not Reported
	Vitamin D [Vitamin D Nos]	C	Not Reported
	Ascorbic Acid	C	Not Reported
	Amitriptyline 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>
23-Jun-2020	17934191	EXPEDITED (15-DAY)		OT	NVSC2020ES150007			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; Off Label Use	Azithromycin			S	Unknown			Novartis
	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17861385	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2020-FR-1241998		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>
Atrioventricular Block Complete; Bundle Branch Block; Conduction Disorder; Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia; Left Ventricular Hypertrophy; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Weight Decreased	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
	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 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>
25-Jun-2020	17943052	EXPEDITED (15-DAY)		DE, OT	ES-BAYER-2020-120629		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>	
Long Qt Syndrome	Chloroquine			S	Oral	250 Mg, Bid		Bayer	
	Kaletra			S	Oral	2 Df, Bid		Not Reported	
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported	
	Enoxaparina Sodica			C	Subcutaneous			Not Reported	
	Ipratropio Bromuro			C	Respiratory (inhalation)			Not Reported	
	Omeprazole			C	Intravenous (not otherwise specified)			Not Reported	
	Ceftriaxona [Ceftriaxone]			C	Intravenous (not otherwise specified)	1 G, Qd		Not Reported	
	Insulina Isofana Humana			C	Subcutaneous			Not Reported	
	Tamiflu			C	Oral	75 Mg, Qid		Not Reported	
	Interferon Beta			C	Subcutaneous	Every 48 Hrs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17943749	EXPEDITED (15-DAY)		CA	FR-MYLANLABS-2020M1058769			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>	
Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Leflunomide			S	Transplacental	Unk		Not Reported	
	Methotrexate			S	Transplacental	Unk		Not Reported	
	Deflazacort			S	Transplacental			Mylan	
	Chloroquine			S	Transplacental	Unk		Mylan	
	Hydroxychloroquine			S	Transplacental	Unk		Mylan	
	Hydrochlorothiazide			S	Transplacental	Unk		Mylan	
	Indometacin			S	Transplacental	Unk		Mylan	

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Methyldopa			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>	
25-Jun-2020	17949999	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1793432		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>	
Fatigue; Nasopharyngitis; Product Dose Omission; Productive Cough; Pyrexia; Respiratory Tract Infection; Sinus Congestion; Sputum Discoloured	Chloroquine				S	Unknown			Not Reported	
	Methotrexate				S	Unknown			Barr	
	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>
29-Jun-2020	17954232	EXPEDITED (15-DAY)		HO, OT	NL-AUROBINDO-AUR-APL-2020-030752		57 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>
Covid-19; Dysarthria; Hemiparesis	Amoxicillin				S	Unknown	Unk		Aurobindo
	Clopidogrel				S	Unknown	Unk		Aurobindo
	Chloroquine				S	Unknown	Unk		Not Reported
	Nadroparin				S	Subcutaneous	3800 International Unit, Daily		Not Reported
	Nadroparin				S	Subcutaneous	5700 International Unit, Daily		Not Reported
	Oxygen				S	Nasal	3 Litre		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17964146	EXPEDITED (15-DAY)		HO, LT, OT	HU-BAYER-2020-127552			Male	HUN
<u>Preferred Term</u>	<u>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;	Chloroquine				S	Oral	500 Mg, Qd		Bayer

FDA Adverse Event Reporting System

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Resuscitation; 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-Jun-2020	17964179	EXPEDITED (15-DAY)		OT	IQ-BAYER-2020-129785		< 1 DAY	Male	IRQ

<u>Preferred Term</u>	<u>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; Low Birth Weight Baby; Premature Baby	Chloroquine			S	Transplacental			Bayer
	Saline-Trose			C	Transplacental			Not Reported
	Paracetamol			C	Transplacental			Not Reported
	Salbutamol			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>
30-Jun-2020	17964195	EXPEDITED (15-DAY)		OT	IQ-BAYER-2020-123593		25 YR	Female	IRQ

<u>Preferred Term</u>	<u>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; Premature Delivery; Product Use In Unapproved Indication	Chloroquine			S	Oral	200 Mg, Bid		Bayer
	Saline-Trose			C	Intravenous (not otherwise specified)			Not Reported
	Paracetamol			C	Parenteral	Paracetamol Infusion 1% W/V, 1 000 Mg/100 MI Infusion)		Not Reported
	Salbutamol			C	Oral	2 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>
03-Jul-2020	17830292	EXPEDITED (15-DAY)		HO, 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>
Atrioventricular Block Complete; Bundle Branch Block; Cardiotoxicity; Conduction Disorder;	Hydroxychloroquine			S	Unknown	400 Mg, Qd, 7.4 Mg/Kg/Day)		Novartis
	Hydroxychloroquine			S				Novartis

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

Decreased Appetite; Drug Ineffective; Dysphagia; Dysphonia; Left Ventricular Hypertrophy; Muscle Disorder; Muscle Injury; Myopathy Toxic; Subacute Cutaneous Lupus Erythematosus; Toxicity To Various Agents	Fenofibrate Chloroquine Chloroquine Ranitidine Clopidogrel Acetylsalicylic Acid Tramadol/Paracetamol Clobetasol	S S S C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	100 Mg, Qd 200 Mg, Qd 300 Mg, Qd 75 Mg, Qd 75 Mg, Qd Unk 1 Application/Day	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>
04-Jul-2020	16350826	EXPEDITED (15-DAY)	HO		IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-208672		69 YR	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>
Urticaria	Letrozole			S	Oral	2.5 Milligram, Daily		Sun
	Omeprazole			S	Oral	20 Milligram, Daily		Sun
	Dibase			S	Oral	50000 Kilo-International Unit, Unk		Not Reported
	Zaroxolyn			S	Oral	10 Milligram, Daily		Not Reported
	Micardis 80 Mg Tablets			S	Oral	80 Milligram, Daily		Not Reported
	Metfonorm			S	Oral	1500 Milligram, Daily		Not Reported
	Chloroquine			S	Oral	250 Milligram, Daily		Not Reported
	Diuresix			S	Oral	10 Milligram, Daily		Not Reported
	Medipo			S	Oral	20 Milligram, Daily		Not Reported
	Kolibri 37,5 Mg / 325 Mg, Comprime Rivestite Con Film			S	Oral	362.5 Milligram, Daily		Not Reported
	Timod			C	Ophthalmic	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>
04-Jul-2020	17980735	EXPEDITED (15-DAY)	CA, OT		US-AUROBINDO-AUR- APL-2020-031106			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>
Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Hydrochlorothiazide			S	Transplacental	Unk		Aurobindo
	Indomethacin			S	Transplacental	Unk		Aurobindo
	Methotrexate			S	Transplacental	Unk		Eugia Pharma
	Deflazacort			S	Transplacental	Unk		Not Reported
	Chloroquine			S	Transplacental	Unk		Not Reported
	Hydroxychloroquine			S	Transplacental	Unk		Not Reported
	Methyldopa			S	Transplacental	Unk		Not Reported
	Leflunomide			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>
04-Jul-2020	17980765	EXPEDITED (15-DAY)		OT	CA-ACCORD-188253			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			S	Unknown	Not Specified		Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Unknown	Solution Subcutaneous		Not Reported
	Leflunomide			S	Unknown			Not Reported
	Myochrysine			S	Unknown	Solution Intramuscular		Not Reported
	Plaquenil			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>
06-Jul-2020	17981753	EXPEDITED (15-DAY)		OT	CA-ACCORD-188258			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; Off Label Use; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Methotrexate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported

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

Adalimumab	S	Unknown	Solution Subcutaneous	Not Reported
Leflunomide	S	Unknown		Not Reported
Hydroxychloroquine	S	Unknown		Not Reported
Infliximab	S	Unknown	Powder For Solution Intravenous	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-Jul-2020	17982853	EXPEDITED (15-DAY)		OT	CA-ACCORD-188556			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; Polyarthritis; Skin Lesion; Uveitis	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Myochrysine			S	Intramuscular	Solution Intramuscular		Not Reported
	Plaquenil			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>
06-Jul-2020	17985590	EXPEDITED (15-DAY)		OT	BR-BAYER-2020-133928			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>
Thrombosis	Chloroquine			S				Bayer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	17986181	EXPEDITED (15-DAY)		CA	US-CADILA HEALTHCARE LIMITED-US-ZYDUS-052576			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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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Methotrexate	S	Transplacental	Unk	Zydus Pharm
	Hydroxychloroquine	S	Transplacental	Unk	Zydus Pharm
	Indomethacin	S	Transplacental	Unk	Zydus Pharm
	Leflunomide	S	Transplacental	Unk	Not Reported
	Deflazacort	S	Transplacental	Unk	Not Reported
	Chloroquine	S	Transplacental	Unk	Not Reported
	Methyldopa	S	Transplacental	Unk	Not Reported
	Hydrochlorothiazide	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>
10-Jul-2020	18005283	EXPEDITED (15-DAY)		OT	IQ-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-252996			Male	IRQ

<u>Preferred Term</u>	<u>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	Salbutamol			S	Transplacental	Unk		Sun
	Chloroquine			S	Transplacental	200 Milligram, Bid		Not Reported
	Paracetamol			S	Transplacental	Unk (Infusion 1% W/V, 1 000 Mg/100 MI Infusion)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	18012921	EXPEDITED (15-DAY)		OT	CA-ACCORD-189944			Female	CAN

<u>Preferred Term</u>	<u>Product</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; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Rash; Retinal Toxicity; Vomiting	Mycophenolic Acid			S	Unknown			Accord
	Methotrexate			S	Oral			Accord
	Azathioprine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Varenicline			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported
	Asaphen			C	Unknown			Not Reported

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

Folic Acid	C			Not Reported
Nasacort	C	Unknown	Metered-Dose (Aerosol)	Not Reported
Pantoprazole	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Synthroid	C	Unknown		Not Reported
Warfarin	C	Oral		Not Reported
Methotrexate	S	Subcutaneous		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>
14-Jul-2020	12825513	EXPEDITED (15-DAY)		OT	BR- GLAXOSMITHKLINE- BR2016GSK144027			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; Anaemia; Circumstance Or Information Capable Of Leading To Medication Error; Concomitant Disease Aggravated; Depression; Fatigue; Headache; Inappropriate Schedule Of Product Administration; Leukopenia; Overdose; Polyarthritis; Product Dose Omission; Social Problem	Benlysta			S		520 Mg, Unk		Glaxosmithkline
	Benlysta			S		560 Mg, Unk		Glaxosmithkline
	Benlysta			S		Unk		Glaxosmithkline
	Methotrexate			S		Unk		Glaxosmithkline
	Chloroquine Phosphate			S		Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	18048599	EXPEDITED (15-DAY)		OT	NVSC2020HR203155		27 YR	Male	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>
Product Use In Unapproved Indication; Still'S Disease	Methotrexate			S	Unknown	Unk		Novartis
	Chloroquine			S	Unknown	Unk		Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)	1 Mg/Kg		Not Reported

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

Benzathine Penicillin G	C	Unknown		Not Reported
Sulphasalazine	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-Jul-2020	18056997	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1802258			Female	CAN

<u>Preferred Term</u>	<u>Product</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; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Rash; Retinal Toxicity; Vomiting	Mycophenolate Mofetil			S	Unknown	2000 Milligram Daily;		Teva
	Azathioprine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Varenicline Tartrate			S	Unknown			Not Reported
	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported
	Asaphen			C	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Nasacort			C	Unknown			Not Reported
	Pantoprazole Magnesium			C	Unknown	40 Milligram Daily;		Not Reported
	Prednisone			C		10 Milligram Daily;		Not Reported
	Synthroid			C	Unknown			Not Reported
	Warfarin 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>
23-Jul-2020	18061325	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1803723			Male	CAN

<u>Preferred Term</u>	<u>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	Azathioprine			S	Unknown	200 Milligram Daily;		Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Oral			Not Reported

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	Methotrexate		S	Unknown				Not Reported	
	Chloroquine		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-Jul-2020	17810882	EXPEDITED (15-DAY)		OT	PL-ROCHE-2602576		30 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>	
Intentional Product Use Issue; Interleukin Level Increased; Off Label Use	Tocilizumab			S	Intravenous (not otherwise specified)	Two Separated Doses 8 Mg/Kg Every 12-24 H		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		For 3 Consecutive Days		Not Reported	
	Thyroxine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	18066163	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA185690			Unknown	ZAF
<u>Preferred Term</u>	<u>Product</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; Hepatitis; Tinnitus	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi	
	Arava			S		20 Mg, Qd		Sanofi	
	Methotrexate			S		Unk		Not Reported	
	Salazopyrin			C		500 Mg, 2x A Day		Not Reported	
	Humira			C		Unk		Not Reported	
	Methotrexate Sodium			C		22.5 Mg, Qw		Not Reported	
	Methotrexate Sodium			C		10 Unk		Not Reported	
	Pritor [Telmisartan]			C		80 Mg, Qd		Not Reported	
	Cyclosporin A			C		50 Mg, Bid		Not Reported	

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Azapress			C		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>
25-Jul-2020	18068072	EXPEDITED (15-DAY)		OT	CA-ACCORD-191896			Male	CAN
<u>Preferred Term</u>	<u>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	Methotrexate			S	Oral			Accord	
	Azathioprine			S	Unknown	1 Every 1 Days		Not Reported	
	Chloroquine			S	Oral			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>
27-Jul-2020	17928465	EXPEDITED (15-DAY)		CA, OT	NVSC2020US173732			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>	
Congenital Hydrocephalus; Foetal Exposure During Pregnancy	Leflunomide			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Methotrexate			S	Transplacental	Maternal Dose:Unknown		Novartis	
	Indomethacin			S	Transplacental	Maternal Dose:Unknown		Not Reported	
	Hydrochlorothiazide			S	Transplacental	Maternal Dose:Unknown		Not Reported	
	Hydroxychloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Deflazacort			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Chloroquine			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Dopamine			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>
27-Jul-2020	18070387	EXPEDITED (15-DAY)		HO, LT, OT	NL-LUPIN PHARMACEUTICALS INC.-2020-03707		35 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>	
Condition Aggravated; Interstitial Lung Disease;	Cefuroxime			S	Unknown	Unk		Lupin	

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Off Label Use; Renal Impairment; Respiratory Failure	Ceftriaxone	S	Unknown	Unk	Lupin
	Chloroquine	S	Oral	600 Milligram (Loading Dose)	Not Reported
	Chloroquine	S	Oral	300 Milligram	Not Reported
	Lopinavir/Ritonavir	S	Unknown	1 Dosage Form, Bid (400/100 Mg)	Not Reported
	Lopinavir/Ritonavir	S			Not Reported
	Everolimus	S	Unknown	3 Milligram (Targeted Trough Concentrations Between 3-8 Microg/L)	Not Reported
	Everolimus	S	Unknown	2 Milligram (Dose Reduced Due To Expected Interaction With Lopinavir/Ritonavir)	Not Reported
	Prednisolone	C	Unknown	7.5 Milligram, Qd	Not Reported
	Acetaminophen	C	Unknown	Unk	Not Reported
	Tramadol	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-Jul-2020	18073507	EXPEDITED (15-DAY)		HO, LT	NL-TEVA-2020-NL-1805884		35 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>	
Acute Kidney Injury; Acute Pulmonary Oedema; Covid-19; Drug Interaction; Hypoxia; Interstitial Lung Disease; Metabolic Acidosis; Off Label Use; Renal Failure; Renal Impairment; Respiratory Alkalosis; Respiratory Failure; Rhabdomyolysis; Toxicity To Various Agents; Transaminases Increased	Everolimus			S	Unknown	6 Milligram Daily; Targeted Trough Concentrations Between 3-8 Microg/L		Teva	
	Everolimus			S	Unknown	4 Milligram Daily; Dose Reduced Due To Expected Interaction With Lopinavir/Ritonavir		Teva	
	Prednisolone			S	Unknown	7.5 Milligram Daily;		Actavis	
	Paracetamol			S	Unknown			Not Reported	
	Cefuroxime			S	Intravenous (not otherwise specified)			Not Reported	
	Chloroquine			S	Oral	Loading Dose		Not Reported	

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

Chloroquine	S	Oral	600 Milligram Daily;	Not Reported
Lopinavir/Ritonavir	S	Unknown	2 Dosage Forms Daily; Lopinavir: 400 Mg; Ritonavir: 100 Mg	Not Reported
Lopinavir/Ritonavir	S	Intravenous (not otherwise specified)		Not Reported
Ceftriaxone	S			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>
27-Jul-2020	18078422	EXPEDITED (15-DAY)		CA, OT	AT-IPCA LABORATORIES LIMITED-IPC-2020-AT- 002316			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Discordant Twin; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Chloroquine Phosphate			S	Transplacental	Unk		Ipca
	Paracetamol			S	Transplacental	Unk		Not Reported
	Ambroxol			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-Jul-2020	18078453	EXPEDITED (15-DAY)		CA, OT	AT-IPCA LABORATORIES LIMITED-IPC-2020-AT- 002317			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Discordant Twin; Foetal Exposure During Pregnancy; Ventricular Septal Defect	Chloroquine Phosphate			S	Transplacental	Unk		Ipca
	Paracetamol			S	Transplacental	Unk		Not Reported
	Ambroxol			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-Jul-2020	17999375	EXPEDITED (15-DAY)		OT	NVSC2020PL186172		30 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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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intentional Product Use Issue; Interleukin Level Increased; Off Label Use	Azithromycin	S	Unknown	500 Mg, Qd	Novartis
	Azithromycin	S	Unknown	250 Mg, Qd	Novartis
	Tocilizumab	S	Intravenous (not otherwise specified)	480 Mg, Wo Separated Doses 8 Mg/Kg Every 12-24 H	Not Reported
	Tocilizumab	S			Not Reported
	Chloroquine	S	Unknown	250 Mg, Bid	Not Reported
	Chloroquine	S	Unknown	500 Mg	Not Reported
	Lopinavir/Ritonavir	S	Unknown	500 Mg	Not Reported
	Lopinavir/Ritonavir	S			Not Reported
	Methylprednisolone	C	Unknown	Unk, For 3 Consecutive Days	Not Reported
	Thyroxine	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-Jul-2020	18095047	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA195533			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<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	Arava			S	Oral	20 Mg		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg		Sanofi
	Methotrexate			C	Unknown	15 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>
01-Aug-2020	17878025	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2020-027726		30 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>
Intentional Product Use Issue; Interleukin Level Increased; Off Label Use	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Chloroquine			S	Unknown	250 Milligram		Not Reported
	Chloroquine			S	Unknown	500 Milligram		Not Reported
	Lopinavir;Ritonavir			S	Unknown	500 Milligram, 0.5 Days		Not Reported

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Tocilizumab	S	Intravenous (not otherwise specified)	480 Milligram	Not Reported
Tocilizumab	S	Intravenous (not otherwise specified)	Unk, Two Separated Doses 8 Mg/Kg Every 12-24 H	Not Reported
Methylprednisolone	C	Unknown	Unk, Once A Day (For 3 Consecutive Days)	Not Reported
Thyroxine	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-Aug-2020	18038110	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-035216		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>	
Psychotic Disorder; Self-Medication; Toxicity To Various Agents	Escitalopram			S	Unknown	10 Milligram, Once A Day, For Several Years		Aurobindo	
	Chloroquine			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-Aug-2020	18101044	EXPEDITED (15-DAY)		OT	CA-ACCORD-193642			Female	CAN
<u>Preferred Term</u>	<u>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; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous	1 Every 1 Weeks		Accord	
	Sulfasalazine			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown	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>
01-Aug-2020	18101397	EXPEDITED (15-DAY)		OT	CA-ACCORD-193629			Female	CAN
<u>Preferred Term</u>	<u>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; Therapeutic Product Effect Incomplete	Methotrexate			S	Subcutaneous			Accord	
	Chloroquine			S	Unknown			Not Reported	

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	Leflunomide		S	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>
04-Aug-2020	18041876	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-191280		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>	
Drug Interaction; Psychotic Disorder	Escitalopram			S		For Several Years		Not Reported	
	Chloroquine			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-Aug-2020	18105639	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04262		65 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>	
Diarrhoea; Nausea; Off Label Use; Vomiting	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			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-Aug-2020	18105643	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04263		40 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>	
Off Label Use; Psychotic Disorder	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			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-Aug-2020	18105645	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04239		24 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>	

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

Off Label Use; Vomiting	Oseltamivir	S	Unknown	Unk		Lupin			
	Azithromycin	S	Unknown	Unk		Lupin			
	Chloroquine	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-Aug-2020	18106044	EXPEDITED (15-DAY)		OT	IN-LUPIN LIMITED-2020-03905		58 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>	
Nausea; Off Label Use; Psychotic Disorder; Vomiting	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			S	Unknown	Unk		Not Reported	
	Lopinavir + Ritonavir			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-Aug-2020	18106052	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04258		40 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>	
Off Label Use; Psychotic Disorder	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			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-Aug-2020	18106054	EXPEDITED (15-DAY)		OT	IN-LUPIN LIMITED-2020-04259		24 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>	
Off Label Use; Vomiting	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			S	Unknown	Unk		Not Reported	

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04-Aug-2020	18106056	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04260		61 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>	
Nausea; Off Label Use; Vomiting	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			S	Unknown	Unk		Not Reported	
	Lopinavir + Ritonavir			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-Aug-2020	18106062	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2020-04261		17 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>	
Diarrhoea; Nausea; Off Label Use; Vomiting	Oseltamivir			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Chloroquine			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-Aug-2020	18108836	EXPEDITED (15-DAY)		OT	IN-BAYER-2020-150740		58 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>	
Acute Psychosis; Nausea; Vomiting	Chloroquine			S				Bayer	
	Oseltamivir			C				Not Reported	
	Azithromycin			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>
04-Aug-2020	18108880	EXPEDITED (15-DAY)		OT	IN-BAYER-2020-150768		40 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>	

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Acute Psychosis	Chloroquine	S	Bayer
	Oseltamivir	C	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>
04-Aug-2020	18108881	EXPEDITED (15-DAY)		OT	IN-BAYER-2020-150763		40 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>
Acute Psychosis	Chloroquine			S				Bayer
	Azithromycin			C				Not Reported
	Oseltamivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	17876338	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2020M1054863		30 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>
Intentional Product Use Issue; Interleukin Level Increased; Off Label Use	Lopinavir/Ritonavir			S	Unknown	500 Milligram, Bid (0.5 Day)		Not Reported
	Azithromycin			S	Unknown	500 Milligram, Qd		Mylan
	Azithromycin			S	Unknown	250 Milligram, Qd		Mylan
	Azithromycin			S	Unknown	500 Milligram, Qd		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	480 Milligram		Mylan
	Tocilizumab			S	Intravenous (not otherwise specified)	Two Separated Doses 8 Mg/Kg Every 12-24 H		Mylan
	Chloroquine			S	Unknown	250 Milligram, Bid (0.5 Day)		Mylan
	Chloroquine			S	Unknown	500 Milligram, Bid (0.5 Day)		Mylan
	Methylprednisolone			C		For 3 Consecutive Days		Mylan
	Thyroxine			C		Unk		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>
05-Aug-2020	18115716	EXPEDITED (15-DAY)		DE, HO	NL-BAYER-2020-155062		68 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>	
Organising Pneumonia	Chloroquine			S		Unk		Bayer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18115726	EXPEDITED (15-DAY)		DE, HO, OT	NL-BAYER-2020-155057		77 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>	
Acute Kidney Injury; Cerebral Infarction; Cerebral Ischaemia; Organising Pneumonia; Pulmonary Embolism	Chloroquine			S		Unk		Bayer	
	Nadroparin			C		87 le/Kg, 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-Aug-2020	18115808	EXPEDITED (15-DAY)		DE, HO, OT	NL-BAYER-2020-155065		74 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>	
Bronchopulmonary Aspergillosis; Organising Pneumonia; Pulmonary Embolism	Chloroquine			S		Unk		Bayer	
	Prednisolone			C		60 Mg, Qd		Not Reported	
	Low Molecular Weight Heparin			C		87 le/Kg, 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-Aug-2020	18119217	EXPEDITED (15-DAY)		DE, HO	NL-BAYER-2020-155064		83 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>	
Organising Pneumonia	Chloroquine			S		Unk		Bayer	

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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-Aug-2020	18119218	EXPEDITED (15-DAY)		DE, HO	NL-BAYER-2020-155063		78 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>	
Organising Pneumonia	Chloroquine			S		Unk		Bayer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18119880	EXPEDITED (15-DAY)		HO, OT	PL-BAYER-2020-156825		43 YR	Male	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>	
Respiratory Failure; Shock Symptom	Chloroquine			S	Oral	500 Mg, Bid		Bayer	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G, Qd		Not Reported	
	Clarithromycin			C	Oral	500 Mg, Bid		Not Reported	
	Furosemide			C				Not Reported	
	Meropenem			C	Intravenous (not otherwise specified)	1 G, Q8hr		Not Reported	
	Linezolid			C	Intravenous (not otherwise specified)	500 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-Aug-2020	18120293	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020297387		66 YR	Female	ZAF
<u>Preferred Term</u>	<u>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; Hypersensitivity; Rheumatoid Arthritis; Synovitis	Salazopyrin			S				Pfizer	
	Chloroquine			S				Not Reported	
	Arava			S				Not Reported	
	Methotrexate			C		25 Mg, Weekly		Not Reported	
	Celebrex			C	Oral	200 Mg		Not Reported	

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07-Aug-2020	17992636	EXPEDITED (15-DAY)		OT	NVSC2020IQ189362			Male	IRQ
<u>Preferred Term</u>	<u>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	Acetaminophen (Paracetamol)			S	Transplacental	Maternal Dose: 1000 Mg Per 100 MI		Novartis	
	Chloroquine			S	Transplacental	Maternal Dose: 200 Mg, Bid		Not Reported	
	Salbutamol			S	Transplacental	Maternal Dose: 2 Mg		Not Reported	
	Saline			S	Transplacental	Unk		Not Reported	
	Glucose			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>
08-Aug-2020	18053883	EXPEDITED (15-DAY)		HO, OT	FR-MACLEODS PHARMACEUTICALS US LTD- MAC2020027370			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>	
Psychotic Disorder; Self-Medication; Toxicity To Various Agents	Escitalopram			S	Unknown	10 Milligram, Qd, For Several Years		Macleods	
	Chloroquine			S	Unknown	Unk, Every		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	17813347	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLABS- 2020M1049414		35 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>	
Acute Kidney Injury; Acute Pulmonary Oedema; Acute Respiratory Distress Syndrome; Condition Aggravated; Cough; Covid-19; Covid-19 Pneumonia; Diarrhoea;	Everolimus			S	Unknown	3 Milligram, Bid		Mylan	
	Everolimus			S		6 Milligram, Qd		Mylan	
	Everolimus			S		3 Milligram, Qd		Mylan	
	Everolimus			S		2 Milligram, Qd		Mylan	
	Everolimus			S		4 Milligram, Qd		Mylan	

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Drug Abuse; Drug	Everolimus	S		2 Milligram, Bid	Mylan
Interaction; Dyspnoea;	Everolimus	S		2 Milligram	Mylan
Headache; Hypoxia;	Everolimus	S	Unknown	3 Milligram, Bid (0.5 Day)	Mylan
Intentional Product	Everolimus	S	Unknown	2 Milligram, Bid (0.5 Day)	Mylan
Misuse; Interstitial Lung	Everolimus	S	Unknown	Dose Reduced Due To	Mylan
Disease; Lung	Everolimus	S	Unknown	Expected Interaction With	
Consolidation;	Everolimus	S	Unknown	3 Milligram, Bid	Mylan
Lymphopenia; Malaise;	Everolimus	S	Unknown	Targeted Trough	Mylan
Metabolic Acidosis;	Everolimus	S	Unknown	Concentrations Between	
Myalgia; Nasal	Everolimus	S	Unknown	3-8 Microg/L.	
Congestion; Nausea; Off				7.5 Milligram, Qd	Mylan
Label Use; Pneumococcal				7.5 Milligram, Qd	Mylan
Infection; Productive				Unk	Not Reported
Cough; Pulmonary	Prednisolone	S	Unknown	Unk	Not Reported
Toxicity; Pyrexia; Rales;	Prednisolone	S	Unknown	Unk	Not Reported
Renal Failure; Renal	Paracetamol	S	Unknown	Unk	Not Reported
Impairment; Respiratory	Paracetamol	S		Unk	Not Reported
Alkalosis; Respiratory	Paracetamol	S		Unk	Not Reported
Failure; Rhabdomyolysis;	Paracetamol	S		Unk	Not Reported
Rhinorrhoea; Tachypnoea;	Paracetamol	S		Unk	Not Reported
Toxicity To Various	Paracetamol	S		Unk	Not Reported
Agents; Transaminases	Paracetamol	S		Unk	Not Reported
Increased;	Paracetamol	S		Unk	Not Reported
Tubulointerstitial Nephritis;	Lopinavir/Ritonavir	S	Unknown	1 Dosage Form, Bid (0.5	Mylan
Vomiting				Day)	
	Chloroquine	S	Oral	600 Milligram, Qd	Mylan
	Chloroquine	S	Oral	600 Milligram (Loading	Mylan
				Dose)	
	Chloroquine	S	Oral	600 Milligram (Loading	Mylan
				Dose)	
	Chloroquine	S	Oral	300 Milligram, Bid	Mylan
	Chloroquine	S	Oral	300 Milligram, Bid	Mylan
	Chloroquine	S		100 Milligram	Mylan
	Kaletra	S	Oral	2 Dosage Form, Qd (Unit	Mylan
				Dose: 400/100 Mg)	
	Kaletra	S	Oral	Unit Dose: 400/100 Mg	Mylan
	Kaletra	S	Oral	2x Per Dag 2 Stuks	Mylan

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Cefuroxime	C	Intravenous (not otherwise specified)	Unk	Mylan
Ceftriaxone	C	Intravenous (not otherwise specified)	Unk	Mylan
Ceftriaxone	C			Mylan
Tramadol	C	Unknown	Unk	Mylan
Tramadol	C		Unk	Mylan
Tramadol	C		Unk	Mylan
Tramadol	C		Unk	Mylan
Tramadol	C		Unk	Mylan

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11-Aug-2020	18137032	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020NL220203		35 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>
Acute Kidney Injury; Acute Pulmonary Oedema;	Prednisolone			S	Unknown	7.5 Mg, Qd		Novartis
Acute Respiratory Distress Syndrome; Condition	Prednisolone			S	Unknown	7.5 Mg, Qd		Novartis
Aggravated; Cough;	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported
Covid-19; Covid-19	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported
Pneumonia; Diarrhoea;	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported
Drug Abuse; Drug Interaction; Dyspnoea;	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported
Headache; Hypoxia;	Acetaminophen (Paracetamol)			S				Not Reported
Intentional Product Misuse; Interstitial Lung Disease; Lung Consolidation;	Everolimus			S	Unknown	3 Mg, Bid (0.5 Day)		Not Reported
Lymphopenia; Malaise;	Everolimus			S	Unknown	3 Mg, Qd		Not Reported
Metabolic Acidosis;	Everolimus			S	Unknown	2 Mg, Bid (0.5 Day)		Not Reported
Myalgia; Nasal Congestion; Nausea; Off Label Use; Pneumococcal Infection; Productive Cough; Pulmonary Toxicity; Pyrexia; Rales;	Everolimus			S	Unknown	2 Mg, Qd		Not Reported
	Everolimus			S	Unknown	3 Mg, Bid		Not Reported
	Everolimus			S	Unknown	4 Mg, Qd		Not Reported
	Everolimus			S	Unknown	6 Mg, Qd		Not Reported
	Everolimus			S	Unknown	2 Mg, Bid		Not Reported
	Everolimus			S	Unknown	0.5 Df, Qd		Not Reported

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Renal Failure; Renal Impairment; Respiratory Alkalosis; Respiratory Failure; Rhabdomyolysis; Rhinorrhoea; Tachypnoea; Toxicity To Various Agents; Transaminases Increased; Tubulointerstitial Nephritis; Vomiting	Everolimus	S	Unknown	1.5 Mg, Qd	Not Reported
	Kaletra	S	Unknown	2 Df, Qd (1 Dosage Form, Bid (0.5 Day))	Not Reported
	Kaletra	S	Oral	2 Df, Qd (Unit Dose: 400/100 Mg)	Not Reported
	Kaletra	S	Oral	4 Df, Qd (2x Per Dag 2 Stuks)	Not Reported
	Kaletra	S	Oral	2 Df, Qd (Unit Dose: 400/100 Mg)	Not Reported
	Kaletra	S	Unknown	05 Df, Qd	Not Reported
	Chloroquine	S	Oral	300 Mg, Bid	Not Reported
	Chloroquine	S	Oral	600 Mg, Qd	Not Reported
	Chloroquine	S	Oral	300 Mg, Bid	Not Reported
	Chloroquine	S	Oral	600 Mg (Loading Dose)	Not Reported
	Chloroquine	S	Oral	150 Mg, Qd	Not Reported

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13-Aug-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	Unknown			Sanofi
	Methotrexate			S	Unknown			Not Reported
	Leflunomide			S	Unknown	Unk		Sanofi
	Chloroquine Phosphate			S	Unknown			Sanofi
	Myochrysine			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>
14-Aug-2020	18117221	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2020-037929		43 YR	Male	POL

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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 Ineffective For Unapproved Indication; Product Use In Unapproved Indication	Linezolid			S	Intravenous (not otherwise specified)	500 Milligram, Two Times A Day		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported
	Chloroquine			S	Unknown	500 Milligram, Two Times A Day		Not Reported
	Clarithromycin			S	Unknown	500 Milligram, Two Times A Day		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Not Reported
	Noradrenaline			S	Unknown	Unk		Not Reported
	Norepinephrine			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>
14-Aug-2020	18149910	EXPEDITED (15-DAY)		HO	AE-IPCA LABORATORIES LIMITED-IPC-2020-AE-002693			Unknown	ARE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Agitation; Delusional Disorder, Unspecified Type; Disorganised Speech; Disorientation; Echolalia; Insomnia; Logorrhoea; Psychomotor Hyperactivity; Tachyphrenia	Chloroquine Tablet			S	Unknown	300 Milligram (Twice A Week)		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>
18-Aug-2020	18160693	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1815983		44 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; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Eye Infection; Inflammation; Ocular Toxicity; Skin Discolouration; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vasculitic Rash	Azathioprine			S	Unknown	200 Milligram Daily;		Not Reported
	Prednisone			S	Unknown	1 Dosage Forms Daily;		Actavis
	Chloroquine			S	Unknown	250 Milligram Daily;		Not Reported
	Mycophenolate Mofetil			S	Oral	3 Milligram Daily;		Not Reported
	Rituximab			S	Intravenous drip			Not Reported
	Rituximab			S				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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18169853	EXPEDITED (15-DAY)		HO, OT	US-IPCA LABORATORIES LIMITED-IPC-2020-US- 002698			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>
Amaurosis; Anxiety; Areflexia; Catatonia; Condition Aggravated; Confusional State; Delusional Perception; Dysphonia; Dysphonia; Facial Paralysis; Hallucinations, Mixed; Insomnia; Magical Thinking; Mydriasis; Neurotoxicity; Paranoia;	Chloroquine			S	Unknown	250 Milligram, Q.W		Ipca
	Olanzapine			S	Unknown	2.5 Milligram, Qd		Not Reported
	Olanzapine			S	Unknown	17.5 Milligram, Qd		Not Reported
	Clonazepam			S	Unknown	Unk		Not Reported
	Diphenhydramine			S	Unknown	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
	Lorazepam			S				Not Reported
	Risperidone			S	Unknown	Unk		Not Reported

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

Persecutory Delusion; Suicidal Ideation; Toxic Encephalopathy; Toxicity To Various Agents; Toxicity To Various Agents; Visual Impairment	Fluoxetine	S	Unknown	Unk	Not Reported
	Benzotropine	S	Unknown	Unk	Not Reported
	Rivastigmine	S	Transdermal	Unk	Not Reported
	Rivastigmine	S	Oral	Unk	Not Reported
	Azithromycin	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-Aug-2020	18176341	EXPEDITED (15-DAY)		HO	US-MYLANLABS- 2020M1072209		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>
Covid-19; Off Label Use	Tacrolimus			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			S	Unknown			Mylan
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid On The First Day		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Bid For The Following 4 Days		Mylan
	Chloroquine			S	Unknown	500 Milligram, Bid		Mylan
	Losartan			C	Unknown	50 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>
21-Aug-2020	17801478	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020NL131829		35 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>
Acute Kidney Injury; Acute Pulmonary Oedema; Acute Respiratory Distress Syndrome; Bacterial Infection; Condition Aggravated; Cough; Covid-19; Covid-19 Pneumonia; Diarrhoea; Drug Interaction; Drug Level Increased; Dyspnoea; Headache;	Everolimus			S	Unknown	6 Milligram, Qd		Novartis
	Everolimus			S	Unknown	4 Milligram, Qd		Novartis
	Lopinavir,Ritonavir			S	Oral	2 Dosage Form, Qd (Unit Dose: 400/100 Mg)		Not Reported
	Lopinavir,Ritonavir			S				Not Reported
	Lopinavir,Ritonavir			S				Not Reported
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported

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

Hypoxia; Interstitial Lung Disease; Lung Consolidation;	Chloroquine	S	Oral	300 Mg, Bid After 600 Mg Loading Dose	Not Reported
Lymphopenia; Malaise;	Chloroquine	S	Oral	100 Mg	Not Reported
Metabolic Acidosis;	Cefuroxime	C	Intravenous (not otherwise specified)	Unk	Not Reported
Myalgia; Nasal Congestion; Nausea; Off Label Use; Pneumococcal Infection; Pneumonitis;	Cefuroxime	C			Not Reported
Product Use In Unapproved Indication;	Ceftriaxone	C	Intravenous (not otherwise specified)	Unk	Not Reported
Productive Cough;	Ceftriaxone	C			Not Reported
Pyrexia; Rales; Renal Failure; Renal Impairment; Renal Injury; Respiratory Alkalosis; Respiratory Failure; Rhabdomyolysis; Rhinorrhoea; Tachypnoea; Toxicity To Various Agents; Transaminases Increased; Tubulointerstitial Nephritis; 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>
21-Aug-2020	18050935	EXPEDITED (15-DAY)		HO, OT	FR-ALLERGAN-2026923US			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; Psychotic Disorder; Self-Medication; Toxicity To Various Agents	Escitalopram Oxalate - Bp			S	Unknown	For Several Years		Allergan	
	Chloroquine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18109848	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020PL214400		43 YR	Male	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>	
Drug Ineffective; Drug	Clarithromycin			S	Oral	500 Mg, Q24h		Novartis	

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

Ineffective For Unapproved Indication; Off Label Use; Respiratory Failure; Shock; Shock Symptom; Therapeutic Product Effect Incomplete	Clarithromycin	S	Oral	1000 Mg, Qd (500 Mg Twice A Day)	Novartis
	Linezolid	S	Intravenous (not otherwise specified)	500 Mg, Q12h	Not Reported
	Linezolid	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
	Ceftriaxone	S			Not Reported
	Chloroquine	S	Oral	1000 Mg, Qd (500 Mg Twice A Day)	Not Reported
	Furosemide	S	Unknown	Unk	Not Reported
	Furosemide	S			Not Reported
	Noradrenaline	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Noradrenaline	S			Not Reported
	Meropenem	S	Intravenous (not otherwise specified)	3 G, Qd	Not Reported
	Meropenem	S	Intravenous (not otherwise specified)	1 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>
21-Aug-2020	18177743	EXPEDITED (15-DAY)		OT	AT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-257816			Female	AUT
<u>Preferred Term</u>	<u>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; Ventricular Septal Defect	Acetaminophen		Y	S	Transplacental	Unk		Ohm Lab	
	Chloroquine			S	Unknown	Unk		Not Reported	
	Ambroxol			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>
21-Aug-2020	18178362	EXPEDITED (15-DAY)		OT	AT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-257815			Female	AUT

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>	
Foetal Exposure During Pregnancy; Ventricular Septal Defect	Acetaminophen		Y	S	Transplacental	Unk		Ohm Lab	
	Chloroquine			S	Transplacental	Unk		Not Reported	
	Ambroxol			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>
24-Aug-2020	18184876	EXPEDITED (15-DAY)		HO, LT	PL-AUROBINDO-AUR-APL-2020-040435		43 YR	Male	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>	
Drug Ineffective; Therapeutic Product Effect Incomplete	Linezolid			S	Intravenous (not otherwise specified)	500 Milligram, Two Times A Day		Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Meropenem			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Not Reported	
	Chloroquine			S	Oral	1000 Milligram, Daily		Not Reported	
	Clarithromycin			S	Oral	1000 Milligram, Daily		Not Reported	
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Furosemide			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-Aug-2020	18187160	EXPEDITED (15-DAY)		OT	ME-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-257871		52 YR	Male	MNE
<u>Preferred Term</u>	<u>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 Injury; Off Label Use	Lopinavir/Ritonavir			S	Unknown	400/100 Mg Twice Daily (For The First 12 Days And 3 Days In Icu)		Not Reported	
	Methylprednisolone			S	Unknown	60-80 Mg Daily (Throughout The Icu Treatment)		Not Reported	

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Ceftriaxone	S	Unknown	(Throughout The Entire Treatment)	Not Reported
Azithromycin	S	Unknown	(Throughout The Entire Treatment)	Sun
Chloroquine	S	Unknown	500 Milligram, Bid (For The First 12 Days Before Icu)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18101022	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR-APL-2020-026592		35 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>	
Acute Kidney Injury; Acute Pulmonary Oedema;	Paracetamol			S	Unknown	Unk		Aurobindo	
Acute Respiratory Distress Syndrome; Condition	Paracetamol			S	Unknown	Unk		Aurobindo	
Aggravated; Cough;	Paracetamol			S				Aurobindo	
Covid-19; Covid-19	Paracetamol			S				Aurobindo	
Pneumonia; Diarrhoea;	Prednisolone			S	Unknown	7.5 Milligram, Once A Day		Aurobindo	
Drug Abuse; Drug Interaction; Dyspnoea;	Prednisolone			S	Unknown	7.5 Milligram, Once A Day		Aurobindo	
Headache; Hypoxia;	Chloroquine			S	Oral	100 Milligram		Not Reported	
Intentional Product Misuse; Interstitial Lung Disease; Lung Consolidation;	Chloroquine			S	Oral	600 Milligram, Once A Day		Not Reported	
Lymphopenia; Malaise; Metabolic Acidosis;	Chloroquine			S	Oral	600 Milligram (600 Mg Loading Dose)		Not Reported	
Myalgia; Nasal Congestion; Nausea; Off Label Use; Pneumococcal Infection; Productive Cough; Pulmonary Toxicity; Pyrexia; Rales;	Everolimus			S	Unknown	300 Milligram, Two Times A Day		Not Reported	
Renal Failure; Renal Impairment; Respiratory Alkalosis; Respiratory Failure; Rhabdomyolysis; Rhinorrhoea; Tachypnoea;	Everolimus			S	Unknown	2 Milligram		Not Reported	
	Everolimus			S	Unknown	2 Milligram, Two Times A Day		Not Reported	
	Everolimus			S	Unknown	3 Milligram, Two Times A Day		Not Reported	
	Everolimus			S	Unknown	3 Milligram, Two Times A Day		Not Reported	
	Everolimus			S	Unknown	2 Milligram, Two Times A		Not Reported	

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Toxicity To Various Agents; Transaminases Increased; Tubulointerstitial Nephritis; Vomiting	Everolimus	S	Unknown	Day	Not Reported
				3 Dosage Form, Two Times A Day, Targeted Trough Concentrations Between 3-8 Microg/L.	
	Everolimus	S	Unknown	4 Milligram, Once A Day	Not Reported
	Everolimus	S	Unknown	2 Dosage Form, Dose Reduced Due To Expected Interaction With Lopinavir/Ritonavir	Not Reported
	Everolimus	S	Unknown	2 Milligram, Two Times A Day	Not Reported
	Everolimus	S	Unknown	2 Milligram, Once A Day	Not Reported
	Lopinavir + Ritonavir	S	Unknown	Unk, 400/100 Milligram, Twice Daily	Not Reported
	Lopinavir + Ritonavir	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported
	Lopinavir + Ritonavir	S			Not Reported
	Alemtuzumab	S	Unknown	15 Milligram, Once A Day	Not Reported
	Kaletra	S	Oral	Unit Dose: 400/100 Mg	Not Reported
	Kaletra	S	Oral	2 Dosage Form, Once A Day	Not Reported
	Kaletra	S	Oral	4 Dosage Form, Once A Day (2x Per Dag 2 Stuks)	Not Reported
	Cefuroxime	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Cefuroxime	S			Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Ceftriaxone	C			Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported
	Tramadol	C			Not Reported
	Tramadol	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>
25-Aug-2020	18194735	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1818280		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>	
Covid-19; Off Label Use	Mycophenolate Mofetil			S	Unknown			Teva	
	Hydroxychloroquine			S	Unknown	800 Milligram Daily; On The First Day		Teva	
	Hydroxychloroquine			S	Unknown	400 Milligram Daily; For The Following 4 Days		Teva	
	Tacrolimus			S	Unknown			Not Reported	
	Chloroquine			S	Unknown	1000 Milligram Daily;		Not Reported	
	Losartan			C	Unknown	100 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>
26-Aug-2020	18197236	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA222617			Unknown	ZAF
<u>Preferred Term</u>	<u>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; Hypersensitivity; Rheumatoid Arthritis; Synovitis	Chloroquine (Salt Not Specified)			S				Sanofi	
	Arava			S				Sanofi	
	Salazopyrin			C				Not Reported	
	Methotrexate			C		Unk		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>
27-Aug-2020	18203513	EXPEDITED (15-DAY)		HO	GB-BAYER-2020-176535		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>	
Rash Erythematous	Chloroquine			S				Bayer	
	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>
27-Aug-2020	18203535	EXPEDITED (15-DAY)		HO, LT	PL-MYLANLABS-2020M1073226		43 YR	Male	POL

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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; Therapeutic Product Effect Incomplete	Clarithromycin			S	Oral	500 Mg Twice A Day		Mylan	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Mylan	
	Meropenem			S	Intravenous (not otherwise specified)	1.0 G Every 8 Hours		Mylan	
	Linezolid			S	Intravenous (not otherwise specified)	500 Mg Every 12 Hours		Mylan	
	Chloroquine			S	Oral	500 Mg Twice A Day		Mylan	
	Furosemide			C		Unk		Mylan	
	Noradrenaline /00127501/			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>
27-Aug-2020	18203554	EXPEDITED (15-DAY)		HO	CN-BAYER-2020- 176837		56 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>	
Electrocardiogram Qt Prolonged	Chloroquine			S	Oral	0.25 G, Bid		Bayer	
	Lopinavir/Ritonavir			S	Oral	400/100 Mg, Bid		Not Reported	
	Arbidol			S	Oral	0.2 G, Tid		Not Reported	
	Pantoprazole			S	Oral	40 Mg, Qd		Not Reported	
	Potassium Chloride			C	Oral	1 G, 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>
31-Aug-2020	18125084	EXPEDITED (15-DAY)		HO, LT, OT	NL-PERRIGO- 20NL010760		35 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>	
Acute Kidney Injury; Acute Pulmonary Oedema; Acute Respiratory Distress Syndrome; Condition Aggravated; Cough;	Paracetamol			S	Unknown	Unk		Perrigo	
	Prednisolone			S	Unknown	7.5 Mg, Qd		Not Reported	
	Lopinavir/Ritonavir			S	Unknown	1 Df		Not Reported	
	Lopinavir/Ritonavir			S				Not Reported	

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

Covid-19; Covid-19 Pneumonia; Diarrhoea; Drug Interaction; Dyspnoea; Headache; Hypoxia; 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; Transaminases Increased; Tubulointerstitial Nephritis; Vomiting	Lopinavir/Ritonavir Everolimus Everolimus Chloroquine Tramadol Tramadol Tramadol Tramadol Tramadol Ceftriaxone Cefuroxime	S S S S C C C C C S S	Unknown Oral Unknown	Targeted Trough Concentrations Between 3-8 Microg/L. 600 Mg Loading Dose Unk Unk	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>
08-Sep-2020	18202975	EXPEDITED (15-DAY)		DE, OT	NVSC2020BG235368		19 YR	Male	BGR

<u>Preferred Term</u>	<u>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; Confusional State; Hallucination; Hypertension; Hypoxia; Hypoxia; Intentional Product Use Issue; Off Label Use; Tachypnoea	Dexamethasone Metamizole Fraxiparine Vancocin Roactemra Roactemra			S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown	Unk (4 Mg/1 MI - 2x2 Amp) Unk (X 2 Capsamp. 500mg/MI 2 MI) 0.6 MI (1 Vial Mg/MI As Prescribed) 1 G, Bid (2x1.0) Unk (400 Mg/20 MI) Unk (200 Mg/20ml)		Novartis Not Reported Not Reported Not Reported Not Reported Not Reported

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

Albunorm	S	Unknown	10 % 1 Total	Not Reported
Albunorm	S	Unknown	Unk	Not Reported
Somazina	S	Unknown	Unk (1000 Mg 4 MI 2x1 Amp)	Not Reported
Calcium Gluconate	S	Unknown	Unk (8.94 Mg/MI - 10 MI - 2x1 Amp)	Not Reported
Sinequan	S	Unknown	Unk (X 2 Caps)	Not Reported
Sterofundin	S	Unknown	Unk (500 L - Eco-Vial - X500 MI)	Not Reported
Degan	S	Unknown	Unk (10 Mg - 2 MI - As Prescribed)	Not Reported
Chlophazolin	S	Unknown	Unk (0.15 Mg/MI - As Prescribed)	Not Reported
Diflazon	S	Unknown	Unk (2 Mg/1 MI - 100 MI - X 2 Vial)	Not Reported
Sodium Chloride	S	Unknown	0.9 % (100 MI Eco-Bottle By Prescription)	Not Reported
Serum Glucose	S	Intravenous (not otherwise specified)	500 MI (By Prescription)	Not Reported
Esomeprazole Magnesium	S	Unknown	40 Mg, Bid (2x1 Vial)	Not Reported
Clexane	S	Unknown	Unk (60 Mg/0.60 MI - X1vial)	Not Reported
Nutriflex Omega Plus	S	Unknown	Unk (875 MI - 2 Pcs)	Not Reported
Meropenem	S	Unknown	1 G, Tid (3x1.0)	Not Reported
Chloroquine	S	Unknown	250 Mg, Bid (2x1 Tablets)	Not Reported
Methylprednisolone	S	Unknown	Unk (40 Mg / 2 MI)	Not Reported
Bromhexine Hydrochloride	S	Unknown	Unk (4 Mg 2 MI - As Prescribed)	Not Reported
Carsil	S	Unknown	Unk (90 Mg * 30 Pcs. - According To The Scheme)	Not Reported
Quamatel	S	Unknown	20 Mg, Bid (2x1 Vial)	Not Reported
Flexidol Relax	S	Unknown	100 MI (5 Mg/MI)	Not Reported

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

Sumamed	S	Unknown	500 Mg (Vial)	Not Reported
Enterol [Attapulgate\Pectin\Phthaly\sulfac etamide]	S	Unknown	Unk (250 Mg * 10 - 2x2 Caps)	Not Reported
Midazolam	S	Unknown	Unk (5 Mg - 5 5 MI - In Perfusion)	Not Reported
Paracetamol	S	Unknown	100 MI (10 Mg/MI)	Not Reported
Meropen	S	Unknown	1000 Mg (3x1.0)	Not Reported
Azitrox	S	Unknown	Unk	Not Reported
Furosemide	S	Unknown	Unk (10 Mg/MI - As Prescribed)	Not Reported
Vitamiin C	S	Unknown	Unk (10 5 5 MI 2x4 Amp)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2020	18240316	EXPEDITED (15-DAY)		HO, LT, OT	NL-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-254165		35 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>
Acute Kidney Injury; Acute Pulmonary Oedema; Acute Respiratory Distress Syndrome; Condition Aggravated; Cough; Covid-19; Covid-19 Pneumonia; Diarrhoea; Drug Ineffective; Drug Interaction; Drug Interaction; Dyspnoea; Headache; Hypoxia; Hypoxia; Immunosuppressant Drug Level Increased; Interstitial Lung Disease; Lung Consolidation; Lymphopenia; Malaise; Metabolic Acidosis; Metabolic Acidosis;	Lopinavir/Ritonavir			S	Unknown	Unk, Bid (400/100 Mg)		Not Reported
	Cefuroxime			S	Intravenous (not otherwise specified)	Unk		Sun
	Cefuroxime			S	Intravenous (not otherwise specified)	()		Sun
	Prednisolone			S	Unknown	7.5 Milligram, Daily		Taro
	Acetaminophen		Y	S	Unknown	()		Ranbaxy
	Nanocort			S	Unknown	7.5 Mg, Qd		Taro
	Everolimus			S	Unknown	3 Milligram, 1dose/12hour		Not Reported
	Everolimus			S	Unknown	2 Milligram, 1dose/12hour		Not Reported
	Everolimus			S	Unknown	4 Milligram, 1dose/12hour		Not Reported
	Chloroquine			S	Oral	600 Mg Loading Dose		Not Reported
	Kaletrakalettra Tablet			S	Oral	2 Dosage Form, Qd (Unit Dose: 400/100 Mg)		Not Reported
	Filmomhuld							

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

Myalgia; Nasal Congestion; Nausea; Off Label Use; Pneumococcal Infection; Productive Cough; Pyrexia; Rales; Renal Failure; Renal Impairment; Renal Impairment; Respiratory Alkalosis; Respiratory Failure; Rhabdomyolysis; Rhinorrhoea; Tachypnoea; Toxicity To Various Agents; Transaminases Increased; Tubulointerstitial Nephritis; Vomiting	200/50mglopinavir/Ritonavir Tablet... Ceftriaxone Tramadol Tramadol	C C C	Unknown Unknown	Unk ()	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>
09-Sep-2020	15986426	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2017GSK149224			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>
Ageusia; Anxiety; Arthralgia; Asthma; Choking; Circumstance Or Information Capable Of Leading To Medication Error; Cough; Decreased Appetite; Decreased Immune Responsiveness; Depressed Mood; Depression; Dyspnoea; Dyspnoea Exertional; Emotional Distress; Exostosis; Eye Disorder; Eye Pain; Fatigue; Fear; Haematoma; Hypotension; Inappropriate Schedule Of Product Administration; Influenza; Limb Injury; Lung Opacity; Malaise;	Benlysta Seretide Cortisone Acetate Chloroquine Velija Deflazacort Alprazolam			S S S S C C C		960 Mg, Unk Unk Unk Unk Unk (60) 6 Mg, Bid Unk		Glaxosmithkline Glaxosmithkline Glaxosmithkline Not Reported Not Reported Not Reported Not Reported

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

Memory Impairment;
Movement Disorder;
Nasopharyngitis;
Nephrolithiasis;
Nervousness; Pain; Pain
In Extremity; Patient
Isolation; Poor Quality
Sleep; Product Availability
Issue; Product Dose
Omission; Pulmonary
Fibrosis; Retinal Disorder;
Skin Discolouration; Social
Problem; Stress; Systemic
Lupus Erythematosus;
Tooth Fracture;
Toothache; Underdose;
Varicose Vein; Vision
Blurred; Visual
Impairment; 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>
09-Sep-2020	18154264	EXPEDITED (15-DAY)		DE	BG-ROCHE-2656505		19 YR	Male	BGR

<u>Preferred Term</u>	<u>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; Intentional Product Use Issue; Off Label Use	Roactemra			S	Unknown	400 Mg/20 MI		Not Reported
	Roactemra			S	Unknown	200 Mg/20ml		Not Reported
	Midazolam			S	Unknown	5 Mg - 5 5 MI - In Perfusion		Not Reported
	Quamatel			S	Unknown	2x1 Vial		Not Reported
	Diflazon			S	Unknown	2 Mg/1 MI - 100 MI - X 2 Vial		Not Reported
	Sodium Chloride			S	Unknown	100 MI Eco-Bottle By Prescription		Not Reported
	Carsil			S	Unknown	90 Mg * 30 Pcs. - According To The Scheme		Not Reported

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

Calcium Gluconate	S	Unknown	8.94 Mg/MI - 10 MI - 2x1 Amp	Not Reported
Vancocin	S	Unknown	2x1.0	Not Reported
Fraxiparine	S	Unknown	1 Vial Mg/MI As Prescribed	Not Reported
Sinequan	S	Unknown	X 2 Caps	Not Reported
Vitamin C	S	Unknown	10 5 5 MI 2x4 Amp	Not Reported
Methylprednisolone	S	Unknown	40 Mg / 2 MI	Not Reported
Serum Glucose	S	Intravenous (not otherwise specified)	By Prescription	Not Reported
Azitrox	S	Unknown		Not Reported
Paracetamol	S	Unknown	10 Mg/MI	Not Reported
Bromhexine	S	Unknown	4 Mg 2 MI - As Prescribed	Not Reported
Chloroquine Phosphate	S	Unknown	2x1 Tablets	Not Reported
Sterofundin	S	Unknown	500 L - Eco-Vial - X500 MI	Not Reported
Enterol (Bulgaria)	S	Unknown	250 Mg * 10 - 2x2 Caps	Not Reported
Meropen	S	Unknown	3x1.0	Not Reported
Dexamethasone	S	Unknown	4 Mg/1 MI - 2x2 Amp	Not Reported
Sumamed	S	Unknown		Not Reported
Degan	S	Unknown	10 Mg - 2 MI - As Prescribed	Not Reported
Somazina	S	Unknown	1000 Mg 4 MI 2x1 Amp	Not Reported
Albunorm	S	Unknown		Not Reported
Esomeprazole	S	Unknown	2x1 Vial	Not Reported
Clexane	S	Unknown	60 Mg/0.60 MI - X1vial	Not Reported
Meropenem	S	Unknown	3x1.0	Not Reported
Nutriflex Omega Plus	S	Unknown	875 MI - 2 Pcs	Not Reported
Furosemide	S	Unknown	10 Mg/MI - As Prescribed	Not Reported
Chlophazolin	S	Unknown	0.15 Mg/MI - As Prescribed	Not Reported
Metamizole	S	Unknown	X 2 Caps Amp. 500mg/MI	Not Reported

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

Flexidol Relax		S		Unknown		2 MI 5 Mg/MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2020	18195219	EXPEDITED (15-DAY)	DE		BG-BAUSCH-BL-2020-024113		19 YR	Male	BGR
<u>Preferred Term</u>	<u>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	Dexamethasone			S	Unknown	4 Mg/1 MI - 2x2 Amp		Bausch And Lomb	
	Sodium Chloride			S	Unknown	100 MI Eco-Bottle By Prescription		Not Reported	
	Serum Glucose			S	Intravenous (not otherwise specified)	By Prescription		Not Reported	
	Meropen (Meropenem)			S	Unknown	Vial (3x1.0)		Not Reported	
	Albunorm			S	Unknown	Vial		Not Reported	
	Sterofundin			S	Unknown	500 L - Eco-Vial - X500 MI		Not Reported	
	Enterol (Saccharomyces Boulardii)			S	Unknown	250 Mg 10 - 2x2 Caps		Not Reported	
	Fraxiparine			S	Unknown	1 Vial Mg/MI As Prescribed		Not Reported	
	Sinequan			S	Unknown	X 2 Caps		Not Reported	
	Sumamed			S	Unknown	Vial		Not Reported	
	Bromhexine			S	Unknown	4 Mg 2 MI - As Prescribed		Not Reported	
	Metamizole			S	Unknown	X 2 Caps Amp. 500mg/MI 2 MI		Not Reported	
	Quamatel			S	Unknown	2x1 Vial		Not Reported	
	Roactemra			S	Unknown	400 Mg/20 MI		Not Reported	
	Roactemra			S	Unknown	200 Mg/20ml		Not Reported	
	Flexidol Relax			S	Unknown	5 Mg/MI		Not Reported	
	Chlophazolin			S	Unknown	0.15 Mg/MI - As Prescribed		Not Reported	
	Calcium Gluconate			S	Unknown	8.94 Mg/MI - 10 MI - 2x1 Amp		Not Reported	

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

Methylprednisolone	S	Unknown	40 Mg / 2 MI	Not Reported
Furosemide	S	Unknown	10 Mg/MI - As Prescribed	Not Reported
Azitrox	S	Unknown		Not Reported
Clexane	S	Unknown	60 Mg/0.60 MI - X1vial	Not Reported
Degan	S	Unknown	10 Mg - 2 MI - As Prescribed	Not Reported
Esomeprazole	S	Unknown	2x1 Vial	Not Reported
Carsil	S	Unknown	90 Mg 30 Pcs. - According To The Scheme	Not Reported
Vancocin	S	Unknown	Vial (2x1.0)	Not Reported
Paracetamol	S	Unknown	10 Mg/MI	Not Reported
Meropenem	S	Unknown	Vial (3x1.0)	Not Reported
Midazolam	S	Unknown	5 Mg - 5 5 MI - In Perfusion	Not Reported
Vitamin C (Ascorbic Acid)	S	Unknown	10 5 5 MI 2x4 Amp	Not Reported
Chloroquine Phosphate	S	Unknown	2x1 Tablets	Not Reported
Somazina (Citicoline)	S	Unknown	1000 Mg 4 MI 2x1 Amp	Not Reported
Diflazon	S	Unknown	Vial, 2 Mg/1 MI - 100 MI - X 2 Vial	Not Reported
Nutriflex Omega Plus	S	Unknown	875 MI - 2 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>
09-Sep-2020	18244725	EXPEDITED (15-DAY)		DS, HO, OT	ZA-LUPIN PHARMACEUTICALS INC.-2020-05563		28 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Haemolytic Anaemia; Exposure During Pregnancy; Haemolysis	Amloc (Amlodipine Besylate)			S	Unknown	10 Milligram, Qd		Lupin
	Calcium Acetate			S	Unknown	1 Gram, Qd		Lupin
	Aldomet [Methyldopa]			S	Unknown	500 Milligram, Bid		Not Reported
	Atenolol			S	Unknown	25 Milligram, Qd		Not Reported
	Vitamin B 12 [Cyanocobalamin]			S	Unknown	3 Dosage Form		Not Reported

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

	Azathioprine	S	Unknown	150 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	5 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	80 Milligram, Qd (1mg/Kg/Day)	Not Reported
	Lanzor	S	Unknown	30 Milligram, Qd	Not Reported
	Nivaquine [Chloroquine]	S	Unknown	200 Milligram, Qd	Not Reported
	Cardura XL	S	Unknown	4 Milligram, Qd (Formulation: Extended Release)	Not Reported
	Zocor	S	Unknown	20 Milligram, Qd	Not Reported
	Polygam	S	Unknown	3 Dosage Form	Not Reported
	Vitamin D [Ergocalciferol]	S	Unknown	800 International Unit, 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-Sep-2020	18247454	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020345924		66 YR	Female	ZAF

<u>Preferred Term</u>	<u>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 Kidney Disease; Drug Ineffective; Psoriasis	Methotrexate			S		12.5 Mg, Weekly		Pfizer
	Chloroquine			S		200 Mg, Daily		Not Reported
	Humira			S		Unk		Not Reported
	Salazopyrin			C		500 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>
11-Sep-2020	14149125	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2017465678		25 YR	Male	ZAF

<u>Preferred Term</u>	<u>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; Drug Ineffective; Peptic Ulcer; Rheumatoid Arthritis; Weight Bearing Difficulty	Methotrexate Sodium			S		25 Ug, Weekly		Pfizer
	Prednisone			S		20 Ug, Daily		Not Reported
	Arava			S	Oral	20 Ug, Daily		Not Reported
	Chloroquine			S		200 Ug, Daily		Not Reported

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

Enbrel Myclic C Subcutaneous 50 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>
11-Sep-2020	18193429	EXPEDITED (15-DAY)		DE, OT	BG-ASTRAZENECA-2020SF05712		19 YR	Male	BGR

<u>Preferred Term</u>	<u>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; Confusional State; Death; Hallucination; Hypertension; Hypoxia; Hypoxia; Intentional Product Use Issue; Off Label Use; Tachypnoea	Esomeprazole			S	Intravenous (not otherwise specified)	40 Mg 2 Inot 1 Vial		Not Reported
	Meropen			S	Unknown	1000 Mg 3 Into 1.0		Not Reported
	Meropen			S	Unknown	3 Into 1.0		Not Reported
	Serum Glucose			S	Intravenous (not otherwise specified)	By Prescription500.0ml Unknown		Not Reported
	Sterofundin			S	Unknown	500 L-Eco-Vial - X500 MI		Not Reported
	Enterol (Saccharomyces Boulardii)			S	Unknown	250 Mg 10 -2x2 Caps		Not Reported
	Fraxiparine			S	Unknown	0.6 MI 1 Vial Mg/MI As Prescribed		Not Reported
	Sinequan			S	Unknown			Not Reported
	Sumamed			S	Unknown	500.0mg Unknown		Not Reported
	Bromhexine			S	Unknown	4 Mg 2 MI - As Prescribed		Not Reported
	Metamizole			S	Unknown	2 Caps Amp. 500mg/MI 2 MI		Not Reported
	Quamatel			S	Unknown	20 Mg 2 Inot 1 Vial		Not Reported
	Flexidol Relax			S	Unknown	100 MI, 5 Mg/MI		Not Reported
	Chlophazolin			S	Unknown	0.15 Mg/MI - As Prescribed		Not Reported
	Calcium Gluconate			S	Unknown	8.94 Mg/MI - 10 MI - 2x1 Amp		Not Reported
	Methylprednisolone			S	Unknown	40 Mg / 2 MI		Not Reported
Furosemide			S	Unknown	10 Mg/MI - As Prescribed		Not Reported	
Azitrox			S	Unknown			Not Reported	
Clexane			S	Unknown	60 Mg/0.60 MI - X1vial		Not Reported	

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

Dexamethasone	S	Unknown	4 Mg/1 MI - 2x2 Amp	Not Reported
Degan	S	Unknown	10 Mg - 2 MI - As Prescribed	Not Reported
Carsil	S	Unknown	90 Mg X 30 Pcs. - According To The Scheme	Not Reported
Vancocin	S	Unknown	1 G, 2 Into 1.0	Not Reported
Paracetamol	S	Unknown	10mg/MI100.0ml Unknown	Not Reported
Sodium Chloride	S	Unknown	0.9 Percent, 100 MI Eco-Bottle By Prescription	Not Reported
Midazolam	S	Unknown	5 Mg - 5 5 MI - In Perfusion	Not Reported
Vitamin C	S	Unknown	10 5 5 MI 2x4 Amp	Not Reported
Chloroquine Phosphate	S	Unknown	250 Mg 2 Into 1 Tablets	Not Reported
Somazina	S	Unknown	1000 Mg 4 MI 2x1 Amp	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2020	18247502	EXPEDITED (15-DAY)	DE		BG-PFIZER INC-2020343658		19 YR	Male	BGR

<u>Preferred Term</u>	<u>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; Intentional Product Use Issue; Off Label Use	Methylprednisolone			S		40 Mg / 2 MI		Pfizer
	Sinequan			S		2 Caps		Pfizer
	Esomeprazole Sodium			S		40 Mg, 2x1 Vial		Pfizer
	Meropenem			S		1 G, 3x1.0		Pfizer
	Meropen			S		1000 Mg, 3x1.0		Unknown
	Quamatel			S		20 Mg, 2x1 Vial		Not Reported
	Bromhexine			S		4 Mg 2 MI - As Prescribed		Not Reported
	Albunorm			S		10 %		Not Reported
	Vitamin C [Ascorbic Acid]			S		10 5 5 MI 2x4 Amp		Not Reported
	Roactemra			S		200 Mg/20ml		Not Reported
	Roactemra			S		400 Mg/20 MI		Not Reported
	Carsil			S		90 Mg * 30 Pcs. -		Not Reported

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			According To The Scheme	
Dexamethasone	S		4 Mg/1 MI - 2x2 Amp	Not Reported
Somazina [Citicoline]	S		1000 Mg 4 MI 2x1 Amp	Not Reported
Vancocin	S		1 G, 2x1.0	Not Reported
Nutriflex Omega Plus	S		875 MI - 2 Pcs	Not Reported
Paracetamol	S		100 MI, 10 Mg/MI	Not Reported
Clexane	S	Unknown	60 Mg/0.60 MI - X1vial	Not Reported
Sodium Chloride	S		0.9 %, 100 MI Eco-Bottle By Prescription	Not Reported
Midazolam	S		5 Mg - 5 5 MI - In Perfusion	Not Reported
Sterofundin	S		500 L - Eco-Vial - X500 MI	Not Reported
Diflazon	S		2 Mg/1 MI - 100 MI - X 2 Vial	Not Reported
Furosemide	S		10 Mg/MI - As Prescribed	Not Reported
Flexidol Relax	S		100 MI, 5 Mg/MI	Not Reported
Chloroquine Phosphate	S		250 Mg, 2x1 Tablets	Not Reported
Serum Glucose	S	Intravenous (not otherwise specified)	500 MI, By Prescription	Not Reported
Azitrox	S		Unk	Not Reported
Sumamed	S		500 Mg	Not Reported
Fraxiparine	S		0.6 MI, 1 Vial Mg/MI As Prescribed	Not Reported
Chlophazolin	S		0.15 Mg/MI - As Prescribed	Not Reported
Metamizole	S		X 2 Caps Amp. 500mg/MI 2 MI	Not Reported
Calcium Gluconate	S		8.94 Mg/MI - 10 MI - 2x1 Amp	Not Reported
Enterol [Saccharomyces Boulardii]	S		200 Mg * 10 - 2x2 Caps	Not Reported
Degan	S		10 Mg - 2 MI - As	Not Reported

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Prescribed

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2020	18257770	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020347161		63 YR	Female	ZAF
<u>Preferred Term</u>	<u>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	Methotrexate			S		12.5 Mg, Weekly		Pfizer	
	Chloroquine			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>
14-Sep-2020	18261124	EXPEDITED (15-DAY)		HO	IL-STRIDES ARCOLAB LIMITED-2020SP010968		84 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>	
Electrocardiogram Q Wave Abnormal;	Memantine Hydrochloride			S	Unknown	Unk		Strides	
Electrocardiogram Qrs Complex Shortened;	Letrozole			S	Unknown	Unk		Not Reported	
Electrocardiogram Qt Prolonged; Torsade De Pointes	Chloroquine Diphosphate			S	Oral	500 Milligram, Bid		Not Reported	
	Bisoprolol			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-Sep-2020	18266647	EXPEDITED (15-DAY)		HO, OT	IL-LUPIN PHARMACEUTICALS INC.-2020-05939		84 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>	
Bradycardia; Torsade De Pointes	Memantine			S	Unknown	Unk		Lupin	
	Bisoprolol			S	Unknown	Unk		Not Reported	
	Letrozole			S	Unknown	Unk		Not Reported	
	Chloroquine Diphosphate			S	Oral	500 Milligram, Bid		Not Reported	
	Apixaban			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-Sep-2020	18234660	EXPEDITED (15-DAY)		DE, OT	BG-MYLANLABS-2020M1076287		19 YR	Male	BGR
<u>Preferred Term</u>	<u>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; Confusional State; Hallucination; Hypertension; Hypoxia; Intentional Product Use Issue; Off Label Use; Tachypnoea	Esomeprazole			S	Unknown	40 Milligram(2x1 Vial)		Mylan	
	Diflazon			S	Unknown	Unk(2 Mg/1 MI - 100 MI - X 2 Vial)		Mylan	
	Sodium Chloride			S	Unknown	0.9 Percent(100 MI Eco-Bottle By Prescription)		Mylan	
	Vitamin C /00008001/			S	Unknown	Unk(10 5 5 MI 2x4 Amp)		Mylan	
	Quamatel			S	Unknown	20 Milligram(2x1 Vial)		Mylan	
	Sinequan			S	Unknown	Unk(X 2 Caps)		Mylan	
	Bromhexine			S	Unknown	Unk(4 Mg 2 MI - As Prescribed)		Mylan	
	Furosemide			S	Unknown	10 Milligram Per Millilitre(10 Mg/MI - As Prescribed)		Mylan	
	Sumamed			S	Unknown	500 Milligram		Mylan	
	Chlophazolin			S	Unknown	0.15 Milligram Per Millilitre(0.15 Mg/MI - As Prescribed)		Mylan	
	Nutriflex Omega Plus			S	Unknown	Unk(875 MI - 2 Pcs)		Mylan	
	Fraxiparine			S	Unknown	0.6 Milliliter(1 Vial Mg/MI As Prescribed)		Mylan	
	Meropen /01250501/			S	Unknown	1000 Milligram(3x1.0)		Mylan	
	Meropen /01250501/			S	Unknown	1 Gram(3x1.0)		Mylan	
	Flexidol Relax			S	Unknown	100 Milliliter(5 Mg/MI)		Mylan	
	Calcium Gluconate			S	Unknown	8.94 Milligram Per Millilitre(8.94 Mg/MI - 10 MI - 2x1 Amp)		Mylan	
	Albunorm			S	Unknown	10 Percent, Total		Mylan	
	Dexamethasone			S	Unknown	Unk(4 Mg/1 MI - 2x2 Amp)		Mylan	

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Degan	S	Unknown	Unk(10 Mg - 2 MI - As Prescribed)	Mylan
Chloroquine Phosphate	S	Unknown	250 Milligram(2x1 Tablets-)	Mylan
Meropenem	S	Unknown	1 Gram(3x1.0)	Mylan
Enterol /00838001/	S	Unknown	Unk(250 Mg 10 - 2x2 Caps)	Mylan
Roactemra	S	Unknown	Unk(200 Mg/20ml)	Mylan
Roactemra	S	Unknown	Unk(400 Mg/20 MI)	Mylan
Vancocin	S	Unknown	1 Gram(2x1.0)	Mylan
Sterofundin	S	Unknown	Unk(500 L - Eco-Vial - X500 MI)	Mylan
Azitrox	S	Unknown	Unk	Mylan
Midazolam	S	Unknown	Unk(5 Mg - 5 5 MI - In Perfusion)	Mylan
Methylprednisolone	S	Unknown	Unk(40 Mg / 2 MI)	Mylan
Metamizole	S	Unknown	Unk(X 2 Caps)	Mylan
Metamizole	S	Unknown	Unk(X 2 Caps Amp. 500mg/MI 2 MI)	Mylan
Clexane	S	Unknown	Unk(60 Mg/0.60 MI - X1vial)	Mylan
Serum Glucose	S	Intravenous (not otherwise specified)	500 Milliliter(By Prescription)	Mylan
Paracetamol	S	Unknown	100 Milliliter(10 Mg/MI)	Mylan
Somazina /00434801/	S	Unknown	1000 Milligram(1000 Mg 4 MI 2x1 Amp)	Mylan
Carsil	S	Unknown	Unk990 Mg 30 Pcs. - According To The Scheme)	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-Sep-2020	18312466	DIRECT						Male	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>	
Hepatic Function Abnormal; Intentional Product Use Issue; Leukopenia; Liver Injury	Methylprednisolone			S	Oral		5 DAY	Not Reported	
	Chloroquine			S	Oral			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>
21-Sep-2020	18164896	EXPEDITED (15-DAY)		CA	NVSC2020AT228202			Female	AUT
<u>Preferred Term</u>	<u>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; Ventricular Septal Defect	Paracetamol			S	Transplacental	Maternal Dose: Unk		Novartis	
	Ambroxol			S	Transplacental	Maternal Dose: Unk		Not Reported	
	Chloroquine			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>
21-Sep-2020	18164908	EXPEDITED (15-DAY)		CA	NVSC2020AT228150			Female	AUT
<u>Preferred Term</u>	<u>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; Ventricular Septal Defect	Paracetamol			S	Transplacental	Maternal Dose: Unk		Novartis	
	Ambroxol			S	Transplacental	Maternal Dose: Unk		Not Reported	
	Chloroquine			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>
22-Sep-2020	18294096	EXPEDITED (15-DAY)		HO	IL-TEVA-2020-IL-1829564		84 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>	
Bradycardia; Off Label Use; Torsade De Pointes	Letrozole			S	Unknown			Teva	
	Memantine			S	Unknown			Teva	
	Bisoprolol			S	Unknown			Not Reported	
	Chloroquine Diphosphate			S	Oral	1000 Milligram Daily;		Not Reported	

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Apixaban			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2020	18300195	EXPEDITED (15-DAY)		OT	ZA-ABBVIE-20K-143-3575044-00		66 YR	Female	ZAF
<u>Preferred Term</u>	<u>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 Kidney Disease; Psoriasis	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2020	18301056	EXPEDITED (15-DAY)		OT	CA-ACCORD-202130		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; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Eye Infection; Inflammation; Ocular Toxicity; Skin Discolouration; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vasculitic Rash	Mycophenolic Acid			S	Oral	1 Every 24 Hours		Accord	
	Azathioprine			S	Unknown	1 Every 24 Hours		Not Reported	
	Prednisone			S	Unknown	1 Every 24 Hours		Not Reported	
	Chloroquine			S	Unknown	1 Every 24 Hours		Not Reported	
	Rituximab			S	Intravenous drip			Not Reported	
	Acetaminophen			C	Oral			Not Reported	
	Amlodipine			C	Unknown			Not Reported	
	Diphenhydramine			C	Oral			Not Reported	
	Iron			C	Unknown			Not Reported	
	Losec			C	Unknown			Not Reported	
	Medrol			C	Unknown			Not Reported	
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported	
	Risedronic Acid			C	Unknown	1 Every 1 Months		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-Sep-2020	18301656	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.- 2020CA026021			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; Arthritis; C-Reactive Protein Increased; Drug Ineffective; Eye Infection; Inflammation; Ocular Toxicity; Off Label Use; Skin Discolouration; Swelling; Therapeutic Product Effect Decreased; Treatment Failure; Vasculitic Rash	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 1 Every 2 Weeks		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	1000 Milligram, 1 Every 2 Weeks		Not Reported
	Azathioprine			S	Unknown	200 Milligram, 1 Every 1 Days		Not Reported
	Chloroquine			S	Unknown	250 Milligram, 1 Every 1 Days		Not Reported
	Mycophenolate Mofetil			S	Oral	3 Milligram, 1 Every 1 Days		Not Reported
	Prednisone			S	Unknown	1 Every 1 Days		Not Reported
	Acetaminophen			C	Oral	650 Milligram		Not Reported
	Amlodipine			C	Unknown			Not Reported
	Diphenhydramine			C	Oral	50 Milligram		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)	100 Milligram		Not Reported
	Risedronate Sodium			C	Unknown	1 Every 1 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>
24-Sep-2020	17672253	EXPEDITED (15-DAY)		HO	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>
Amnesia; Arthritis; Contraindicated Product Administered; Delirium;	Simponi			S	Subcutaneous			Not Reported
	Cosentyx			S	Unknown			Not Reported

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Dislocation Of Vertebra;	Enbrel	S	Unknown	Not Reported
Drug Hypersensitivity;	Hydroxychloroquine	S	Unknown	Not Reported
Drug Ineffective; Drug	Hydroxychloroquine	S		Not Reported
Intolerance; Drug	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Tolerance Decreased;				
Infection; Rheumatoid	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Arthritis; Seronegative				
Arthritis; Therapeutic				
Product Effect Decreased;	Sulfasalazine	S	Unknown	Not Reported
Treatment Failure; Type 2	Methotrexate	S	Unknown	Not Reported
Diabetes Mellitus; Wound				
Infection	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
	Leflunomide	S	Unknown	Not Reported
	Erythromycin	C	Unknown	Not Reported
	Morphine	C	Topical	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>
24-Sep-2020	18306865	EXPEDITED (15-DAY)		HO	IL-CELLTRION-2020-IL-000031		84 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>	
Bradycardia; Torsade De Pointes	Memantine (Non-Specific)			S				Celltrion	
	Chloroquine Diphosphate			S		500 Mg Twice Daily		Not Reported	
	Letrozole			S				Not Reported	
	Bisoprolol			S				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>
29-Sep-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	Not Reported
Blood Pressure Increased;	Simponi	S	Subcutaneous	Not Reported
Contraindicated Product	Remicade	S	Intravenous (not	Not Reported
Administered; Drug			otherwise specified)	
Hypersensitivity; Drug	Actemra	S	Unknown	Not Reported
Ineffective; Drug	Arava	S	Unknown	Not Reported
Intolerance; Dyspnoea;	Arava	S	Unknown	Not Reported
Gout; Hepatic Enzyme	Cimzia	S	Subcutaneous	Not Reported
Increased; 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	Methotrexate	S	Oral	Not Reported
Disorder; 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
Product Use Issue;	Leflunomide	S	Oral	Not Reported
Rheumatoid Arthritis;	Leflunomide	S	Unknown	Not Reported
Sensitivity To Weather	Azathioprine	S	Unknown	Not Reported
Change; Swelling;	Chloroquine	S	Unknown	Not Reported
Synovitis; Therapeutic	Ciclosporin	S	Unknown	Not Reported
Product Effect Decreased;	Otezla	S	Unknown	Not Reported
Weight Increased				

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

Rituximab	S	Intravenous (not otherwise specified)	Not Reported
Allopurinol	C	Unknown	Not Reported
Clomipramine	C	Unknown	Not Reported
Folic Acid	C	Unknown	Not Reported
Pantoloc /01263201/	C	Unknown	Not Reported
Zyloprim	C	Unknown	Not Reported
Fentanyl	C	Unknown Transdermal Patch	Not Reported
Fentanyl	C		Not Reported
Fentanyl Citrate	C	Unknown Liquid Epidura	Not Reported
Depo-Medrol	C	Intra-articular	Not Reported
Esomeprazole Magnesium Trihydrate	C		Not Reported
Naproxen	C		Not Reported