

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[CHLOROQUINE,CHLOROQUINE HYDROCHLORIDE,CHLOROQUINE PHOSPHATE,CHLOROQUINE SALICYLATE,CHLOROQUINE SULFATE]			
Active Moiety:				
FDA Received Date:	From:	05-May-2015	To:	05-May-2020
MedDRA® Version* :	23.0			
Total Cases**:	600			
Number of Pages:	230			

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>
19-May-2015	11127536	EXPEDITED (15-DAY)	Y	DE, HO	IPC201505-000291		28 YR	Female	BGD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Blood Albumin Decreased; Body Temperature Increased; Cough; Dehydration; Electrolyte Imbalance; Sepsis; Tachycardia; Toxic Epidermal Necrolysis	Chloroquine Phosphate (Chloroquine Phosphate) (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>
22-May-2015	11131051	EXPEDITED (15-DAY)		DE, HO	IN-CIPLA LTD.-2015IN04053			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>	
Respiratory Failure; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Lamotrigine			S	Oral	50 Mg, Qd		Cipla	
	Sodium Valproate			S		300 Mg, Qd		Not Reported	
	Clonazepam			S		0.25 Mg, Qd		Not Reported	
	Chloroquine			S		Unk		Not Reported	
	Cefixime Plus Potassium Clavulanate			S				Not Reported	
	Paracetamol			S		Unk		Not Reported	
	Primaquine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2015	11212757	EXPEDITED (15-DAY)		DS	BR-ABBVIE-15K-020-1411098-00		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>	
Arthralgia; Drug Ineffective; Myopia; Nephrolithiasis; Pain In	Humira			S	Subcutaneous			Not Reported	
	Chloroquine			S	Unknown			Not Reported	

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Extremity; Pain In	Atenolol	C	Oral	Not Reported
Extremity; Paraesthesia;	Levothyroxine Sodium	C	Oral	Not Reported
Visual Impairment	Rosuvastatin Sodium	C	Oral	Not Reported
	Vitamin D Nos	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2015	11241829	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC- 2015-IPXL-00714		56 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>
Cataract Subcapsular; Colour Vision Tests Abnormal Red-Green; Macular Pigmentation; Nephropathy; Toxicity To Various Agents; Visual Acuity Reduced	Chloroquine Phosphate			S	Unknown	2.6 Mg/Kg, Daily		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>
06-Jul-2015	11246474	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Dispensed To Wrong Patient; Wrong Patient Received Product	Chloroquine Hcl			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11283935	EXPEDITED (15-DAY)		OT	IN-SA-2015SA102342		56 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>
Acquired Pigmented Retinopathy; Colour Vision Tests Abnormal Red- Green; Maculopathy; Optic Atrophy; Product Use In	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported

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Unapproved Indication;
Visual Acuity Reduced;
Visual Impairment

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2015	11303032	EXPEDITED (15-DAY)		HO, LT	GB-WATSON-2015-15123		75 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>	
Acute Kidney Injury; Atrioventricular Block Complete; Renal Impairment	Bisoprolol (Unknown)			S	Oral	10 Mg, Daily		Actavis Elizabeth	
	Chloroquine (Unknown)			S	Oral	250 Mg, Daily		Watson	
	Beclometasone Dipropionate			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	
	Ranitidine			C	Unknown	Unk		Not Reported	
	Salbutamol Sulfate			C	Unknown	Unk		Not Reported	
	Simvastatin			C	Unknown	Unk		Not Reported	
	Spironolactone			C	Unknown	Unk		Not Reported	
	Tiotropium Bromide			C	Unknown	Unk		Not Reported	
	Aspirin			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-Jul-2015	11308192	EXPEDITED (15-DAY)		HO	GB-TEVA-579599ACC		75 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>	
Acute Kidney Injury; Atrioventricular Block Complete; Renal Impairment	Bisoprolol			S	Oral	10 Milligram Daily;		Duramed	
	Chloroquine			S	Oral	250 Milligram Daily;		Not Reported	
	Beclometasone Dipropionate			C				Not Reported	
	Ramipril			C				Not Reported	
	Ranitidine			C				Not Reported	
	Salbutamol Sulfate			C				Not Reported	
	Simvastatin			C				Not Reported	
	Spironolactone			C				Not Reported	
	Tiotropium Bromide			C				Not Reported	
	Aspirin			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2015	11312475	EXPEDITED (15-DAY)		HO, LT	PHHY2015GB085640		75 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>
Acute Kidney Injury; Atrioventricular Block Complete; Renal Impairment	Bisoprolol			S	Oral	10 Mg, Qd		Novartis
	Chloroquine			S	Oral	250 Mg, Qd		Not Reported
	Beclometasone Dipropionate			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported
	Tiotropium Bromide			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2015	11316210	EXPEDITED (15-DAY)		HO, LT	GB-AUROBINDO-AUR- APL-2015-06628		75 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>
Acute Kidney Injury; Atrioventricular Block Complete; Renal Impairment	Bisoprolol 10 Mg			S	Oral	10 Mg, Once A Day		Aurobindo
	Chloroquine			S	Oral	250 Mg, Once A Day		Not Reported
	Beclometasone Dipropionate			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Spironolactone			C	Unknown			Not Reported
	Tiotropium Bromide			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11321387	EXPEDITED (15-DAY)		HO, LT	GB-MYLANLABS-2015M1024356			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Atrioventricular Block Complete; Renal Impairment	Bisoprolol			S	Oral	10 Mg, Qd		Not Reported	
	Chloroquine			S	Oral	250 Mg, Qd		Not Reported	
	Beclometasone Dipropionate			C				Not Reported	
	Ramipril			C				Not Reported	
	Ranitidine			C				Not Reported	
	Salbutamol Sulfate			C				Not Reported	
	Simvastatin			C				Not Reported	
	Spironolactone			C				Not Reported	
	Tiotropium Bromide			C				Not Reported	
	Aspirin /00002701/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2015	11397788	EXPEDITED (15-DAY)		HO	CONCORDIA PHARMACEUTICALS INC.-CO-PL-KR-2015-181		74 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delusion; Electroencephalogram Abnormal; Hallucination, Auditory; Psychotic Disorder	Hydroxychloroquine			S	Oral			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>
25-Aug-2015	11415346	EXPEDITED (15-DAY)		HO	PL-WATSON-2015-17848		70 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>	
Drug Ineffective; Gastrointestinal Disorder	Hydrocortisone (Unknown)			S	Topical	Unk		Watson	
	Chloroquine (Unknown)			S	Oral	250 Mg, Unk		Watson	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2015	11422744	EXPEDITED (15-DAY)		HO	PL-SA-2015SA128144		70 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>	
Drug Ineffective; Gastrointestinal Disorder	Chloroquine (Salt Not Specified)			S	Oral			Not Reported	
	Hydrocortisone Salt Not Specified			S	Topical			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2015	11444978	EXPEDITED (15-DAY)		HO	PL-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-102112			Unknown	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; Gastrointestinal Disorder	Hydrocortisone			S	Topical			Ranbaxy	
	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>
04-Sep-2015	11458741	EXPEDITED (15-DAY)		OT	CA-TEVA-590818USA		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased	Chloroquine (Mah Unknown)			S		Variable Dosages		Teva	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Hydroxychloroquine			S		Variable Dosages		Not Reported	
	Arava			C				Not Reported	
	Arava			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11486343	EXPEDITED (15-DAY)		OT	HU-SA-2015SA134072		32 YR	Unknown	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>	

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Bone Marrow Toxicity; Drug Ineffective; Gastrointestinal Disorder	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Chloroquine (Salt Not Specified)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Azathioprine	C		Not Reported
	Adalimumab	C		Not Reported
	Etanercept	C		Not Reported
	Golimumab	C		Not Reported
	Cyclosporine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2015	11183466	NON-EXPEDITED		OT	US-AMGEN- USASP2015056347		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Leukopenia; Liver Function Test Increased; Weight Increased	Enbrel			S	Unknown	25 Mg/0.5ml, Unk		Amgen
	Xeljanz			S	Oral	5 Mg, Twice Daily		Not Reported
	Xeljanz			S				Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Oxycodone			S	Unknown	Unk		Not Reported
	Reglan /00041901/			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Actemra			S	Unknown	162 Mg, Qwk		Not Reported
	Codeine Sulfate			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Keflex /00145501/			S	Unknown	Unk		Not Reported
	Arava			S	Unknown	Unk		Not Reported
	Metamucil /00029101/			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported
	Bayer			C		81 Mg, Unk		Not Reported
	Orencia			C		Unk		Not Reported

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

Metamucil /00029101/

C

0.52 G, Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2015	11533831	EXPEDITED (15-DAY)		OT	HU-ORION CORPORATION ORION PHARMA-TREX2015- 0575		32 YR	Unknown	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>
Bone Marrow Toxicity; Drug Ineffective; Gastrointestinal Disorder	Methotrexate			S	Oral			Not Reported
	Methotrexate			S				Not Reported
	Chloroquine			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Prednisolone			C	Unknown	>7.5 Mg Continuously		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2015	11550281	EXPEDITED (15-DAY)		OT	US-HOSPIRA-3018035		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Leukopenia; Liver Function Test Increased; Weight Increased	Xeljanz			S	Oral	Twice Daily		Not Reported
	Codeine Sulfate			S	Unknown			Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			S	Unknown	25 Mg/0.5ml		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Keflex /00145501/			S	Unknown			Not Reported
	Reglan /00041901/			S	Unknown	Unk		Not Reported
	Bayer Aspirin			C				Not Reported
	Orencia			C				Not Reported
	Arava			S	Unknown			Not Reported
	Oxycodone			S	Unknown			Not Reported
	Vitamin D /00107901/			C				Not Reported
	Actemra			S	Unknown			Not Reported

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

Metamucil /00029101/	C	Not Reported
Metamucil /00029101/	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Oct-2015	11184163	NON-EXPEDITED			US-PFIZER INC-2015193704		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Liver Function Test Increased	Azithromycin			S		Unk		Pfizer
	Enbrel			S		Unk (25 Mg/0.5 MI)		Pfizer
	Oxycodone			S		10 Mg, Unk		Pfizer
	Codeine Sulfate			S		15 Mg, Unk		Not Reported
	Keflex			S		250 Mg, Unk		Not Reported
	Reglan			S		10 Mg, Unk		Not Reported
	Chloroquine			S		Unk		Not Reported
	Actemra			S		162 Mg, Weekly		Not Reported
	Bactrim			S		Unk (400 Mg Sulfamethoxazole-800mg Trimethoprim)		Not Reported
	Oxycontin			S		10 Mg, Unk		Not Reported
	Oxycodone Hcl			S		10 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2015	11589459	EXPEDITED (15-DAY)		OT	US-EGALET US INC-US-2015EGA000527			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Leukopenia; Liver Function Test Increased; Weight Increased	Oxycodone Hydrochloride			S		Unk		Egalet
	Enbrel			S		25 Mg/0.5ml,Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Xeljanz			S		1 Df, Daily		Not Reported
	Xeljanz			S	Oral	5 Mg, Twice Daily		Not Reported
	Methotrexate			S		Unk		Not Reported

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

Reglan /00041901/	S	Unk	Not Reported
Azithromycin	S	Unk	Not Reported
Actemra	S	162 Mg, Qwk	Not Reported
Codeine Sulphate	S	Unk	Not Reported
Chloroquine	S	Unk	Not Reported
Keflex /00145501/	S	Unk	Not Reported
Arava	S	Unk	Not Reported
Metamucil /00029101/	C	Unk	Not Reported
Metamucil /00029101/	C	0.52 G, Unk	Not Reported
Vitamin D /00107901/	C	Unk	Not Reported
Bayer Aspirin	C	81 Mg, Unk	Not Reported
Orencia	C	Unk	Not Reported
Multivitamins	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2015	10347413	EXPEDITED (15-DAY)		OT	HU-SA-2014SA094805		74 YR	Female	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>
Condition Aggravated; Drug Ineffective; Herpes Zoster; Pneumonia; Product Use In Unapproved Indication; Rash Pruritic; Rheumatoid Nodule; Urticaria	Arava			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Chloroquine			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Simponi			S	Subcutaneous	1/Month		Not Reported
	Zaldiar			C	Oral	3 X1		Not Reported
	Methylprednisolone			C				Not Reported
	Methylprednisolone			C		Tapered Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2015	11652939	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS		36 YR	Female	USA

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

INC.-CO-PL-US-2015-30

<u>Preferred Term</u>	<u>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; Pain; Red Blood Cell Sedimentation Rate Increased; Suicidal Ideation	Plaquenil			S	Unknown			Not Reported	
	Methotrexate			S			Not Reported		
	Chloroquine Phosphate			S			Not Reported		
	Arava			S			Not Reported		
	Zorvolex			C			Not Reported		
	Humira			C			Not Reported		
	Enbrel			C			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2015	11655015	EXPEDITED (15-DAY)		OT	KR-WATSON-2015-22130		53 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maculopathy	Chloroquine (Unknown)			S	Unknown	400 Mg, Daily		Watson	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Oct-2015	11663597	EXPEDITED (15-DAY)		CA	FR-ROCHE-1650689			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>	
Anophthalmos; Paternal Exposure During Pregnancy	Cellcept			S	Transplacental			Not Reported	
	Nivaquine			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2015	11686709	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-15-01		35 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>	
Cough; Leukopenia; Nasal Congestion; Neutropenia;	Chloroquine			S	Unknown			Hikma	

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

White Blood Cell
Morphology Abnormal

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2015	11649916	EXPEDITED (15-DAY)		HO	BR- GLAXOSMITHKLINE- BR2015133901		21 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastroenteritis	Blinded Chloroquine			S	Oral	Unk		Glaxosmithkline	
	Blinded Chloroquine			S	Oral	Unk		Glaxosmithkline	
	Blinded No Therapy			S	Oral	Unk		Glaxosmithkline	
	Blinded Placebo			S	Oral	Unk		Glaxosmithkline	
	Blinded Primaquine			S	Oral	Unk		Glaxosmithkline	
	Blinded Primaquine			S	Oral	Unk		Glaxosmithkline	
	Blinded Tafenoquine			S	Oral	Unk		Glaxosmithkline	
	Blinded Tafenoquine			S	Oral	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>
04-Nov-2015	11697051	EXPEDITED (15-DAY)		OT	CA-TEVA-604991ACC		44 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>	
Feeling Hot; Musculoskeletal Discomfort; Neuropathy Peripheral	Novo-Chloroquine Tab 250 Mg			S	Unknown			Teva	
	Novo-Chloroquine Tab 250 Mg			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11720244	EXPEDITED (15-DAY)		HO, OT	US-ENDO PHARMACEUTICALS INC.-2015-003698		21 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>	
Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Pre-	Prednisone Tablets			S	Unknown	5-20mg		Not Reported	
	Cellcept			S	Unknown			Not Reported	

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Eclampsia; Premature Delivery; Preterm	Azathioprine	S	Unknown					Not Reported
Premature Rupture Of Membranes; Systemic Lupus Erythematosus; Urinary Tract Infection	Chloroquine	S	Unknown	125-250mg				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2015	11720255	EXPEDITED (15-DAY)		HO	US-ENDO PHARMACEUTICALS INC.-2015-003701		< 1 DAY	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>	
Escherichia Sepsis; Foetal Exposure During Pregnancy; Meningitis; Premature Baby	Prednisone Tablets			S	Transplacental	5-20mg		Not Reported	
	Cellcept			S	Transplacental			Not Reported	
	Azathioprine			S	Transplacental			Not Reported	
	Chloroquine			S	Transplacental	125-250mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2015	11733345	EXPEDITED (15-DAY)		DS, HO, OT	BR-JNJFOC- 20151108049			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>	
Arthralgia; Joint Swelling; Visual Impairment; Wound	Remicade			S	Intravenous (not otherwise specified)			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>
16-Nov-2015	11745518	DIRECT		OT			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Drug Hypersensitivity; Drug Ineffective; Hypoaesthesia	Chloroquine Ph 500mg Alaren			S	Oral	1 Tablet 500 Mg 1 Pill Weekly Taken By Mouth		Unknown	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11751686	EXPEDITED (15-DAY)		HO, OT	PHHY2015NZ148126		56 YR	Female	NZL
<u>Preferred Term</u>	<u>Product</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; Malaria; Plasmodium Vivax Infection; Treatment Failure	Riamet			S	Unknown	4 Df, Bid		Not Reported	
	Doxycycline			S	Unknown	100 Mg, Qd		Novartis	
	Doxycycline			S	Unknown	100 Mg, Qd		Novartis	
	Primacin			S	Unknown	30 Mg, Qd		Not Reported	
	Primacin			S	Unknown	45 Mg, Qd		Not Reported	
	Malarone			S	Unknown	4 Df, Qd		Not Reported	
	Chloroquine			S	Unknown	2 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11787525	EXPEDITED (15-DAY)		HO	FR-SA-2015SA188950		27 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>	
Altered State Of Consciousness; Electrocardiogram Qt Prolonged	Stilnox			S	Oral			Not Reported	
	Nivaquine			S	Oral	2 Platelets (About 2 Grams)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2015	11788922	EXPEDITED (15-DAY)		OT	IN-WATSON-2015-18378		56 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>	
Acquired Pigmented Retinopathy; Optic Atrophy	Chloroquine (Unknown)			S	Unknown	2.6 Mg/Kg, Daily		Watson	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2015	11794451	EXPEDITED (15-DAY)		HO, OT	US-AMNEAL PHARMACEUTICALS-2015AMN00197		1 DAY	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacteraemia; Escherichia Sepsis; Maternal Drugs Affecting Foetus; Meningitis; Premature Baby	Azathioprine			S		50 Mg, 1x/Day		Amneal
	Cellcept			S		1500 Mg, 2x/Day		Not Reported
	Prednisolone			S		5-20mg Daily		Not Reported
	Choloroquine			S		125-250mg Daily		Not Reported
	Cephalosporin			S		Unk		Not Reported
	Cephalosporin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2015	11812087	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-2015-IPXL-01233		< 1 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Meningitis Neonatal; Premature Baby; Sepsis Neonatal	Chloroquine Phosphate			S	Transplacental	Unk		Impax
	Azathioprine			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental			Not Reported
	Cephalosporin			S	Transplacental	Unk		Not Reported
	Cellcept			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-Dec-2015	11812363	EXPEDITED (15-DAY)		OT	US-IMPAX LABORATORIES, INC-2015-IPXL-01232		21 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>
Amniotic Cavity Infection; Condition Aggravated; Exposure During Pregnancy; Pre-Eclampsia; Preterm Premature Rupture Of Membranes; Urinary Tract Infection	Chloroquine Phosphate			S	Unknown	(125-250mg) Daily		Impax
	Cellcept			S	Unknown	1500 Mg, Bid		Not Reported
	Azathioprine			S	Unknown	50 Mg, Daily		Not Reported
	Prednisone			S	Unknown	(5-20mg) Daily		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2015	11770167	EXPEDITED (15-DAY)		OT	PL-BAXTER-2015BAX062140		62 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>	
Disease Progression	Endoxan			S	Unknown	Too Low Dose		Baxter	
	Endoxan			S	Unknown			Baxter	
	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>
21-Dec-2015	11855171	EXPEDITED (15-DAY)		HO, OT	CO-WATSON-2015-13762		36 YR	Female	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Complete; Cardiomyopathy; Syncope	Chloroquine (Unknown)			S	Unknown	250 Mg, Daily		Watson	
	Prednisolone			C	Unknown	5 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2015	11868213	EXPEDITED (15-DAY)		OT	CA-WATSON-2015-14901			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maculopathy; Rash	Chloroquine (Unknown)			S	Unknown	250 Mg, Daily		Watson	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2016	11890092	EXPEDITED (15-DAY)		OT	BR-ABBVIE-10P-020-0663473-00			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; Eyelid Disorder; Musculoskeletal Pain; Tendon Rupture; Vision Blurred	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Chloroquine			S	Oral			Not Reported	

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Diclofenac Sodium	C	Oral	Not Reported
Folic Acid	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2016	11892741	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED- E2B_00000004		7 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>
Glucose-6-Phosphate Dehydrogenase Deficiency; Haemolysis; Methaemoglobinaemia	Chloroquine Phosphate Primaquine			S S		Unk Unk		Ipca Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2016	11909606	NON-EXPEDITED			US-NATCO PHARMA LIMITED-1046370		48 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>
Deafness; Tinnitus	Chloroquine Phosphate Tablets, 500 Mg Multivitamin			S C	Oral			Natco Pharma Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2016	11443497	EXPEDITED (15-DAY)		OT	DE-AMGEN- DEUNI2015085305		65 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>
Asthma; Cough; Dyspnoea	Etanercept			S	Unknown	50 Mg, Qwk		Amgen
	Plaquenil /00072602/			S	Unknown	200 Mg, Daily		Not Reported
	Chloroquine			S	Unknown	200 Mg, Daily		Not Reported
	Azathioprin			S	Unknown	50 Mg, Weekly		Not Reported
	Formatis			C		Unk		Not Reported
	Novopulmon			C		Unk		Not Reported
	Singulair			C		Unk		Not Reported

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	Salbutamol		C		Unk		Not Reported		
	Omeprazole		C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2016	11928277	EXPEDITED (15-DAY)		OT	DE-IMPAX LABORATORIES, INC- 2016-IPXL-00008		45 YR	Male	TGO
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction; Drug Ineffective; Haemolysis; Hepatic Necrosis; Ileus Paralytic; Multiple Organ Dysfunction Syndrome; Osteonecrosis; Plasmodium Falciparum Infection	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>
25-Jan-2016	11948023	NON-EXPEDITED			US-IMPAX LABORATORIES, INC- 2015-IPXL-00386			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>	
Decreased Appetite; Fatigue; Hyperreflexia; Nausea; Weight Decreased; White Blood Cell Count Decreased	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Keppra			S	Unknown	Unk		Not Reported	
	Depakote			S	Unknown	Unk		Not Reported	
	Valcyte			S	Unknown	Unk		Not Reported	
	Cimetidine			S	Unknown	Unk		Not Reported	
	Temozolomide			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2016	12047845	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-CO-PL-US-2016-03			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Arthralgia; Ataxia;	Plaquenil	S	Unknown	Not Reported
Complement Factor	Prednisone	S	Unknown	Not Reported
Decreased; Fatigue;	Chloroquine	S	Unknown	Not Reported
Palpitations; Rebound	Quinacrine	C		Not Reported
Effect; Systemic Lupus				
Erythematous; Tinnitus				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2016	12076908	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC201602- 000060		56 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>
Cataract Subcapsular; Optic Atrophy; Retinopathy; Toxicity To Various Agents	Chloroquine Phosphate			S				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>
16-Feb-2016	12079768	EXPEDITED (15-DAY)			CO-SA-2016SA023994		42 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Arava			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Chloroquine			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12100978	EXPEDITED (15-DAY)		OT	NG-IPCA LABORATORIES LIMITED-IPC201602- 000242		28 YR	Female	NGA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy; Ototoxicity	Chloroquine Phosphate			S	Intramuscular			Ipca

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2016	12155187	DIRECT	Y	HO			47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia Of Chronic Disease; Blood Magnesium Decreased; Chronic Obstructive Pulmonary Disease; Hypokalaemia; Norovirus Test Positive; Pneumonia	Ixempro 40mg/M2			S	Intravenous (not otherwise specified)			Not Reported	
	Chloroquine 100mg/5ml			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2016	12203396	EXPEDITED (15-DAY)		OT	PHHY2016BR037482		49 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>	
Blindness	Voltaren			S	Unknown			Novartis	
	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>
30-Mar-2016	12221535	EXPEDITED (15-DAY)		DE	PK-SA-2016SA057593			Male	PAK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myocardial Infarction; Toxicity To Various Agents	Chloroquine (Salt Not Specified)			S	Oral	3-4 Tablets Mixed In Meals		Not Reported	
	Chloroquine (Salt Not Specified)			S	Oral	Several Tablets Mixed In Meal		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2016	12245240	NON-EXPEDITED			US-PFIZER INC-2016171944			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Hypersensitivity	Norvasc	S	Unk	Pfizer
	Revatio	S	Unk	Pfizer
	Medrol	S	Unk	Pfizer
	Spiriva	S	Unk	Not Reported
	Pantoprazole	S	Unk	Pfizer
	Hydroxyzine Pamoate	S	Unk	Pfizer
	Cymbalta	S	Unk	Not Reported
	Cipro	S	Unk	Not Reported
	Metoprolol Tartrate	S	Unk	Not Reported
	Chloroquine	S	Unk	Not Reported
	Warfarin	S	Unk	Not Reported
	Imuran	S	Unk	Not Reported
	Nitrofurantoin	S	Unk	Not Reported
	Advair	S	Unk	Not Reported
	Tramadol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12254444	EXPEDITED (15-DAY)		HO	GB-IPCA LABORATORIES LIMITED-IPC201603- 000360		30 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>
Generalised Tonic-Clonic Seizure; Joint Dislocation	Chloroquine Phosphate			S				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>
19-Apr-2016	12281100	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC201604- 000369		45 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>
Maculopathy; Optic Atrophy; Toxicity To	Chloroquine Phosphate			S	Oral			Ipca

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

Various Agents

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Apr-2016	12300154	EXPEDITED (15-DAY)		HO	GB-SA-2016SA078530		30 YR	Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Comminuted Fracture; Generalised Tonic-Clonic Seizure; Humerus Fracture; Intentional Product Misuse; Joint Dislocation; Joint Swelling; Loss Of Consciousness; Movement Disorder; Musculoskeletal Pain; Pain; Tremor	Chloroquine (Salt Not Specified)			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-May-2016	12346863	EXPEDITED (15-DAY)		OT	IN-SA-2016SA086900		45 YR	Male	IND
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fundoscopy; Macular Pigmentation; Maculopathy; Optic Atrophy; Optic Atrophy; Optic Nerve Injury; Pupillary Reflex Impaired; Retinal Pigment Epitheliopathy; Strabismus; Visual Acuity Tests Abnormal; Visual Impairment	Chloroquine (Salt Not Specified)			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2016	12362532	EXPEDITED (15-DAY)		OT	GB-IMPAX LABORATORIES, INC- 2016-IPXL-00490		30 YR	Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Generalised Tonic-Clonic Seizure; Humerus Fracture; Joint Dislocation; Overdose	Chloroquine Phosphate	S	Unknown	500 Mg, 2 /Day	Impax
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12364113	EXPEDITED (15-DAY)		HO	SI-SA-2016SA087787		76 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>
Atrial Septal Defect Acquired; Central Venous Pressure Increased; Cyanosis Central; Dyspnoea; Ejection Fraction Decreased; Electrocardiogram Abnormal; Hypoxia; Left Atrial Enlargement; N-Terminal Prohormone Brain Natriuretic Peptide Increased; Oxygen Saturation Decreased; Pleural Effusion; Product Use In Unapproved Indication; Pulmonary Arterial Pressure Increased; Pulmonary Hypertension; Restrictive Cardiomyopathy; Right Atrial Enlargement; Right Ventricular Enlargement; Right-To-Left Cardiac Shunt; Systolic Dysfunction; Troponin I Increased; Ventricular Hypertrophy	Chloroquine Phosphate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12364181	EXPEDITED (15-DAY)		HO	SI-SA-2016SA093137		72 YR	Female	SVN

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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>	
Atrioventricular Block Complete; Product Use In Unapproved Indication	Chloroquine Phosphate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2016	12407779	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2016GSK075130		21 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 Ineffective; Lupus Nephritis	Benlysta			S		Unk		Glaxosmithkline	
	Cyclophosphamide			S		Unk		Not Reported	
	Chloroquine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2016	12415185	EXPEDITED (15-DAY)		HO, OT	PL-ALKEM-001656		44 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>	
Central Nervous System Lymphoma; Necrotising Herpetic Retinopathy	Mycophenolic Acid			S	Intravenous (not otherwise specified)			Alkem	
	Methylprednisolone			S				Not Reported	
	Arechin			S				Not Reported	
	Prednisone			S		Previously Received Oral Prednisone (40 Mg/Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12419632	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC-2016-IPXL-00553		45 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>	
Maculopathy; Optic Atrophy; Product Use In Unapproved Indication; Strabismus	Chloroquine Phosphate			S	Oral	150 Mg, Daily		Impax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2016	12439889	EXPEDITED (15-DAY)		DE	PK-IPCA LABORATORIES LIMITED-IPC201605- 000473			Male	PAK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myocardial Infarction; Overdose; Toxicity To Various Agents	Chloroquine Phosphate Chloroquine Phosphate			S S				Ipca 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-Jun-2016	12448543	EXPEDITED (15-DAY)		OT	BR-IMPAX LABORATORIES, INC- 2016-IPXL-00612		62 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Cellulitis	Chloroquine Phosphate			S	Unknown	Since 1 Year, Twice A Week		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>
14-Jun-2016	12462424	EXPEDITED (15-DAY)		DE, OT	FR-ASTRAZENECA- 2002CG01629		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Complete; Cardio- Respiratory Arrest; Cardiomyopathy; Coma; Conduction Disorder; Overdose	Chloroquine Omeprazole Bayer Prednisone			S S S	Oral Oral Oral			Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2016	12496733	EXPEDITED (15-DAY)		OT	FR-SA-2016SA115360		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Bundle Branch Block Left; Chest	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	

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Pain

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jun-2016	12465638	EXPEDITED (15-DAY)		OT	FR-WATSON-2016-12287		66 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Angina Pectoris; Bundle Branch Block Left	Chloroquine (Unknown)			S	Unknown	100 Mg, Daily		Watson	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12504182	EXPEDITED (15-DAY)		HO, OT	SI-IPCA LABORATORIES LIMITED-IPC201606-000529		76 YR	Female	SVN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Central Venous Pressure Increased; Cyanosis Central; Dyspnoea; Hypoxia; Pleural Effusion; Restrictive Cardiomyopathy; Right-To-Left Cardiac Shunt	Chloroquine Phosphate			S				Ipca	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Jun-2016	12504667	EXPEDITED (15-DAY)		HO, OT	SI-IMPAX LABORATORIES, INC-2016-IPXL-00648		76 YR	Female	SVN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Atrioventricular Block; Restrictive Cardiomyopathy; Right Ventricular Failure; Right-To-Left Cardiac Shunt	Chloroquine Phosphate			S	Unknown	250 Mg, Daily		Impax	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Jun-2016	9203909	EXPEDITED (15-DAY)		HO	HU-SANOFI-AVENTIS-2013SA034291		56 YR	Female	HUN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Atrioventricular Block Complete; Biopsy Muscle Abnormal; Blood Lactate Dehydrogenase Increased; Bradycardia; Brain Natriuretic Peptide Increased; Cardiac Arrest; Cardiomyopathy; Dizziness; Echocardiogram Abnormal; Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged; Hypotension; Muscular Weakness; Myopathy; Overdose; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Fibrillation	Chloroquine (Salt Not Specified)			S	Unknown	Supramaximal Dose		Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12508295	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2015GSK139770			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Condition Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Benlysta			S		900 Mg, Unk		Glaxosmithkline
	Benlysta			S		900 Unk, Unk		Glaxosmithkline
	Benlysta			S		900 Unk, Unk		Glaxosmithkline
	Benlysta			S		900 Mg, Unk		Glaxosmithkline
	Chloroquine Phosphate			S				Glaxosmithkline
	Plaquenil			S				Not Reported
	Methotrexate			S				Glaxosmithkline

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2016	12547150	EXPEDITED (15-DAY)		DE	PK-IMPAX LABORATORIES, INC- 2016-IPXL-00323			Male	PAK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myocardial Infarction; Toxicity To Various Agents	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>
12-Jul-2016	12549480	EXPEDITED (15-DAY)		DE	BE-IMPAX LABORATORIES, INC- 2016-IPXL-00718		26 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Interaction; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	2 G, 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>
18-Jul-2016	12466250	EXPEDITED (15-DAY)		OT	PHHY2016CA079802		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 Sandoz			S	Subcutaneous	0.9 MI, Qw		Novartis	
	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-Jul-2016	12571092	EXPEDITED (15-DAY)		DE, HO	BR-SA-2016SA130142		20 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 Pain; Brain Herniation; Coma; Coma Scale Abnormal; Disseminated Tuberculosis; Granulomatous Liver Disease; Hepatic	Prednisone			S	Intravenous (not otherwise specified)			Not Reported	
	Chloroquine Phosphate			S	Unknown			Not Reported	
	Methylprednisolone Hydrogen Succinate			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	

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Necrosis; Lung Infiltration;
Papilloedema; Peritonitis;
Pneumonia; Pyrexia;
Sepsis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2016	12571112	EXPEDITED (15-DAY)		DE	BR-SA-2016SA130166		14 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 Pain; Chest X-Ray Abnormal; Cough; Disseminated Tuberculosis; Dyspnoea; Lymphadenopathy; Productive Cough; Pyrexia; Respiratory Failure; Somnolence; Stupor	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Methylprednisolone Hydrogen Succinate			S	Intravenous (not otherwise specified)			Not Reported
	Chloroquine Phosphate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2016	12571054	EXPEDITED (15-DAY)		DE, OT	BR-SA-2016SA130161		19 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>
Confusional State; Cough; Disseminated Tuberculosis; Headache; Lung Infiltration; Pneumonia; Pulmonary Alveolar Haemorrhage; Pulmonary Granuloma; Pulmonary Necrosis; Sepsis	Methylprednisolone Hydrogen Succinate			S	Intravenous (not otherwise specified)	Three Pulses		Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)	0.5-1.0 G/M2		Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

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Alendronate		C		Not Reported						
Calcitonin		C		Not Reported						
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2016	10276616	EXPEDITED (15-DAY)		OT	BR-ABBVIE-14P-020-1253503-00			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>		
Arthropathy; Exostosis; Eyelid Disorder; Intervertebral Disc Protrusion; Intervertebral Disc Protrusion; Ligament Rupture; Meniscus Injury; Osteoarthritis; Pain; Spinal Disorder	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported		
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported		
	Chloroquine			S	Unknown			Not Reported		
	Piroxicam/Dipirone/Famotidine/C			C	Oral			Not Reported		
	odeine/Nortriptyline									
	Prednisone			C	Oral			Not Reported		
	Clonazepam			C	Oral			Not Reported		
	Miracalcio Vit D			C	Oral	Every Night		Not Reported		
	Alendronate Sodium			C	Oral			Not Reported		
	Methotrexate			C	Oral	Every Wednesday		Not Reported		
	Methotrexate			C					Not Reported	
	Folic Acid			C	Oral	Every Thursday		Not Reported		
	Folic Acid			C					Not Reported	
	Omeprazole			C	Oral			Not Reported		
	Cefalina			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
05-Aug-2016	12596794	EXPEDITED (15-DAY)		DE, LT, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-120908		15 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>		
Confusional State; Disseminated Tuberculosis; Irritability	Prednisone			S	Unknown	60 Mg, Daily		Mutual		
	Prednisone			S	Unknown	15 Mg, Daily		Mutual		
	Azathioprine			S	Unknown	150 Mg, Daily		Not Reported		

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		Azathioprine		S	Unknown	100 Mg, Daily			Not Reported
		Chloroquine		S	Unknown	250 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-Aug-2016	12594548	EXPEDITED (15-DAY)		DE	BR-WATSON-2016-16201		15 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>	
Confusional State; Disseminated Tuberculosis; Irritability	Chloroquine (Unknown)			S	Unknown	250 Mg, Daily		Watson	
	Azathioprine (Unknown)			S	Unknown	100 Mg, Daily		Not Reported	
	Azathioprine (Unknown)			S	Unknown	150 Mg, Daily		Not Reported	
	Prednisone (Unknown)			S	Unknown	15 Mg, Daily		Watson	
	Prednisone (Unknown)			S	Unknown	60 Mg, Daily		Watson	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2016	12680119	EXPEDITED (15-DAY)		DE, OT	BR-MYLANLABS-2016M1035677			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disseminated Tuberculosis; Hepatotoxicity	Azathioprine			S	Unknown	150 Mg, Qd		Not Reported	
	Azathioprine			S	Unknown	100 Mg, Qd		Not Reported	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	60 Mg, Qd		Mylan	
	Prednisone			S	Unknown	15 Mg, Qd		Mylan	
	Chloroquine			S	Unknown	250 Mg, Qd		Mylan	
	Isoniazid			S	Unknown	Unk		Mylan	
	Pyrazinamide			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>
24-Aug-2016	12680145	EXPEDITED (15-DAY)		DE, HO, OT	BR-MYLANLABS-2016M1035701			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Brain Herniation; Coma; Disseminated Tuberculosis; Sepsis	Azathioprine	S	Unknown	100 Mg, Qd	Not Reported				
	Prednisone	S	Unknown	60 Mg, Qd	Mylan				
	Chloroquine	S	Unknown	250 Mg/Day; Continued For Next 2 Years	Mylan				
	Methylprednisolone	S	Intravenous (not otherwise specified)	1 G, Qd	Mylan				
	Metronidazole	C	Unknown	Unk	Mylan				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2016	12682964	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Label Issue	Chloroquine Phosphate Chloroquine Phosphate			S	Oral			Rising Pharmaceuticals	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2016	12704177	EXPEDITED (15-DAY)		DE	BR-FRESENIUS KABI- FK201605930		20 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>	
Disseminated Tuberculosis	Methylprednisolone (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
	Prednisone			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Metronidazole			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2016	12715846	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2016-04146			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amlodipine			S	Unknown			Aurobindo	

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Hydroxyzine	S	Unknown		Aurobindo
Pantoprazole	S	Unknown		Aurobindo
Metoprolol	S	Unknown	Unk	Aurobindo
Tramadol	S	Unknown		Aurobindo
Cymbalta	S	Unknown		Not Reported
Cipro /00697201/	S	Unknown		Not Reported
Norvasc	S	Unknown		Not Reported
Medrol /00049601/	S	Unknown		Not Reported
Nitrofurantoin	S	Unknown		Not Reported
Advair	S	Unknown		Not Reported
Spiriva	S	Unknown		Not Reported
Warfarin	S	Unknown		Not Reported
Revatio	S	Unknown		Not Reported
Chloroquine	S	Unknown		Not Reported
Imuran /00001501/	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2016	12719595	EXPEDITED (15-DAY)	HO		PHHY2016FR121189		62 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest;	Ritaline Lp			S	Oral	20 Mg, Once/Single		Not Reported
Cardiogenic Shock; Coma;	Zopiclone			S	Oral	67.5 Mg, Once		Not Reported
Confusional State;	Bisoprolol Fumarate			S	Oral	11.25 Mg, Once		Novartis
Electrocardiogram Qrs	Spironolactone			S	Oral	750 Mg, Once		Not Reported
Complex Prolonged;	Chloroquine			S	Oral	3400 Mg, Once/Single		Not Reported
Hypokalaemia; Language	Seresta			S	Oral	160 Mg, Once		Not Reported
Disorder; Miosis;	Mianserin Hydrochloride			S	Oral	750 Mg, Once		Not Reported
Ventricular Tachycardia	Cardensiel			C	Unknown	1.25 Mg, Unk		Not Reported
	Mianserine			C	Unknown	10 Mg/Dl, Qod		Not Reported

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Solian	C	Unknown	50 Mg, Qod	Not Reported
Climaston	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2016	12475984	EXPEDITED (15-DAY)		HO, OT	BR-UCBSA-2016012797		29 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>
Hemiplegia; Mouth Injury; Pregnancy; Rheumatoid Arthritis; Swollen Tongue; Tracheostomy Malfunction; Vocal Cord Disorder; Vocal Cord Paralysis	Certolizumab Pegol			S		200 Mg, Ev 15 Days		Ucb
	Certolizumab Pegol			S		Unk		Ucb
	Chloroquine			S	Oral	Unk		Not Reported
	Prednisone			C	Oral	10 Mg, Once Daily (Qd)		Not Reported
	Methotrexate			C	Oral	200 Mg, Weekly (Qw)		Not Reported
	Folic Acid			C	Oral	Unk		Not Reported
	Tylenol [Acetaminophen\Codeine Phosphate]			C	Oral	30 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>
13-Sep-2016	12739575	EXPEDITED (15-DAY)		DE, HO	BR-IPCA LABORATORIES LIMITED-IPC201609- 000748		20 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>
Brain Herniation; Coma; Disseminated Tuberculosis; Papilloedema; Peritonitis; Pneumonia; Pneumoperitoneum; Sepsis	Chloroquine Phosphate			S				Ipca
	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12739586	EXPEDITED (15-DAY)		DE, HO	BR-IPCA LABORATORIES LIMITED-IPC201609- 000749		19 YR	Female	BRA

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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>
Confusional State; Disseminated Tuberculosis; Lumbar Vertebral Fracture; Pneumonia; Sepsis	Chloroquine Phosphate			S				Ipca
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Cyclophosphamide			S	Intravenous (not otherwise specified)			Not Reported
	Azathioprine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12739592	EXPEDITED (15-DAY)		DE, HO	BR-IPCA LABORATORIES LIMITED-IPC201609- 000751		14 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 Pain; Disseminated Tuberculosis; Somnolence; Stupor	Chloroquine Phosphate			S				Ipca
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12739595	EXPEDITED (15-DAY)		DE, HO	BR-IPCA LABORATORIES LIMITED-IPC201609- 000750		15 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 Pain; Confusional State; Disseminated Tuberculosis; Irritability; Pleurisy; Vomiting	Chloroquine Phosphate			S				Ipca
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Azathioprine			S				Not Reported
	Azathioprine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2016	12760533	EXPEDITED (15-DAY)		OT	MX-SA-2016SA168850		43 YR	Female	MEX

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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>	
Sjogren'S Syndrome; Xerophthalmia	Arava			S	Oral			Not Reported	
	Aralen			S	Oral			Not Reported	
	Methotrexate			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2016	9805223	EXPEDITED (15-DAY)		OT	BR-AMGEN- BRASP2014000901		51 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>	
Blindness; Drug Ineffective; Emotional Disorder; Injection Site Erythema; Pain; Visual Impairment	Enbrel			S	Unknown	50 Mg, Once Weekly		Amgen	
	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>
18-Nov-2016	12957050	EXPEDITED (15-DAY)		DE, HO	SN-BAUSCH-BL-2016- 027877		3 YR	Female	SEN
<u>Preferred Term</u>	<u>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 Distress; Sputum Purulent	Metronidazole			S	Unknown			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Ceftriaxone			C				Not Reported	
	Spiramycine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2016	11324269	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2015249939		60 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Diarrhoea; Hypoaesthesia; Pain; Post Procedural Complication; Swelling; Therapeutic Product Effect	Methotrexate Sodium			S	Oral	Unk		Pfizer	
	Sulfasalazine			S		Unk		Pfizer	
	Plaquenil			S		Unk		Not Reported	
	Chloroquine			S		Unk		Not Reported	

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Incomplete; Thrombosis	Remicade	S	Unk	Not Reported
	Arava	S	Unk	Not Reported
	Xeljanz	C	Oral	5 Mg, 2x/Day
				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2016	12982676	EXPEDITED (15-DAY)		OT	NL- GLAXOSMITHKLINE- NL2016GSK175836			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>	
Headache; Myalgia; Pathogen Resistance; Pyrexia; Thrombocytopenia; Treatment Failure	Atovaquone + Proguanil Hydrochloride Chloroquine Chloroquine			S S S	 Oral Oral	 900 Mg, Unk 450 Mg, Unk		Glaxosmithkline Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2016	12982697	EXPEDITED (15-DAY)		OT	NL- GLAXOSMITHKLINE- NL2016GSK175881			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>	
Headache; Myalgia; Pathogen Resistance; Pyrexia; Thrombocytopenia; Treatment Failure	Atovaquone + Proguanil Hydrochloride Chloroquine Chloroquine			S S S		 600 Mg, Unk 300 Mg, Unk		Glaxosmithkline Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2016	12990208	EXPEDITED (15-DAY)		HO	IN-SA-2016SA213354		7 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>	
Chromaturia; Cyanosis; Fatigue; Haemoglobin Decreased; Haemolysis; Hypotension; Jaundice; Methaemoglobinaemia; Ocular Icterus; Oxygen	Chloroquine (Salt Not Specified) Chloroquine (Salt Not Specified) Primaquine Primaquine			S S S S	Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported	

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Saturation Decreased;
Pallor; Pallor;
Splenomegaly

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	12991876	EXPEDITED (15-DAY)		OT	AE-BAUSCH-BL-2016-030115		30 YR	Male	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>	
Condition Aggravated; Drug Interaction	Chlordiazepoxide			S	Unknown			Not Reported	
	Omeprazole			S	Unknown			Not Reported	
	Chloroquine			S	Unknown	Over 3 Days		Not Reported	
	Primaquine			S	Unknown	Over 14 Days		Not Reported	
	Mefloquine			S	Unknown	Three Divided Doses Over 24 Hours		Not Reported	
	Domperidone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	12992039	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC-2016-IPXL-02218		7 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>	
Haemolysis; Methaemoglobinaemia	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Primaquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	13004923	EXPEDITED (15-DAY)		OT	AE-LUPIN PHARMACEUTICALS INC.-2016-05421		30 YR	Male	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>	
Chorioretinopathy; Drug Interaction	Mefloquine			S	Unknown	1500 Mg 3 Divided Doses Over 24 Hours		Not Reported	
	Omeprazole			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	

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	Chlordiazepoxide-Clidinium Bromide	S	Unknown		Not Reported
	Chloroquine	S	Unknown	2500 Mg Over 3 Days	Not Reported
	Primaquine	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13007209	EXPEDITED (15-DAY)		OT	AE-MYLANLABS-2016M1053124			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>
Chorioretinopathy; Diplopia; Dizziness; Drug Interaction	Omeprazole			S	Unknown			Not Reported
	Mefloquine			S	Oral	1500mg In Three Divided Doses Over 24 Hours		Mylan
	Chloroquine			S	Unknown	2500 Mg Over 3 Days		Mylan
	Primaquine			S	Unknown	15 Mg/Day Over 14 Days		Mylan
	Domperidone			S	Unknown			Mylan
	Chlordiazepoxide Hcl And Clidinium Bromide			S	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2016	13008485	EXPEDITED (15-DAY)		OT	AE-GLENMARK PHARMACEUTICALS INC, USA.-2016GMK02525		30 YR	Male	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>
Condition Aggravated; Drug Interaction	Omeprazole			S	Unknown	Unk		Glenmark
	Domperidone			S	Unknown	Unk		Not Reported
	Chlordiazepoxide Hcl And Clidinium Bromide			S	Unknown	Unk		Not Reported
	Mefloquine			S	Unknown	1500 Mg, Unk		Not Reported
	Primaquine			S	Unknown	15 Mg, Od		Not Reported
	Chloroquine			S	Unknown	2500 Mg, Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	13013649	EXPEDITED (15-DAY)		OT	PHHY2016US166780		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>	
Chorioretinopathy; Dizziness; Nausea; Vomiting	Mefloquine			S	Unknown	500 Mg, Tid		Novartis	
	Chloroquine			S	Unknown	2500 Mg		Not Reported	
	Primaquine			S	Unknown	15 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2016	13020707	EXPEDITED (15-DAY)		OT	AE-SA-2016SA220778		30 YR	Male	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>	
Chorioretinopathy; Condition Aggravated; Diplopia; Dizziness; Drug Interaction; Fluorescence Angiogram Abnormal; Fundoscopy Abnormal; Macular Scar; Metamorphopsia; Nausea; Optical Coherence Tomography Abnormal; Vision Blurred; Visual Acuity Reduced; Vomiting	Omeprazole			S	Unknown			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown	Over 3 Days		Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Primaquine			S	Unknown			Not Reported	
	Mefloquine			S	Unknown			Not Reported	
	Chlordiazepoxide/Clidinium Bromide			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13027178	EXPEDITED (15-DAY)		CA, DS	BR-SA-2016SA222347			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Auditory Neuropathy Spectrum Disorder; Brain Stem Auditory Evoked Response Abnormal; Deafness; Foetal Exposure During	Chloroquine (Salt Not Specified)			S	Transplacental			Not Reported	
	Gentamicin			S	Transplacental			Not Reported	

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Pregnancy; Otoacoustic
Emissions Test Abnormal

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13037237	EXPEDITED (15-DAY)		HO, LT	FR-IMPAX LABORATORIES, INC- 2016-IPXL-02288		32 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>	
Cardiac Failure Acute; Cardiogenic Shock; Poisoning Deliberate	Chloroquine Phosphate			S	Oral	9.5 G, Total		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>
18-Dec-2016	13037851	EXPEDITED (15-DAY)		DS, OT	AE-DEXPHARM- 20162359		30 YR	Male	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>	
Chorioretinopathy; Dizziness	Omeprazole			S				Not Reported	
	Mefloquine			S				Not Reported	
	Chloroquine			S				Not Reported	
	Primaquine			S				Not Reported	
	Domperidone			S				Not Reported	
	Chlordiazepoxide/Clidinium Bromide			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2016	13028126	EXPEDITED (15-DAY)		HO	US-JNJFOC- 20161212063		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>	
Condition Aggravated;	Risperidone			S	Unknown			Not Reported	
Drug Ineffective For	Risperidone			S	Unknown			Not Reported	
Unapproved Indication;	Chloroquine			S	Unknown			Not Reported	
Drug Interaction; Off Label	Olanzapine			S	Unknown	Tapered Off		Not Reported	
Use; Toxic	Olanzapine			S	Unknown			Not Reported	
Encephalopathy; Toxicity	Olanzapine			S	Unknown			Not Reported	
To Various Agents	Olanzapine			S	Unknown			Not Reported	

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Olanzapine	S	Unknown		Not Reported
Olanzapine	S	Unknown	Tapered Off	Not Reported
Olanzapine	S	Unknown		Not Reported
Lorazepam	S	Unknown		Not Reported
Lorazepam	S	Unknown		Not Reported
Lorazepam	S	Unknown		Not Reported
Lorazepam	S	Unknown		Not Reported
Lorazepam	S	Unknown		Not Reported
Lorazepam	S	Unknown		Not Reported
Benzotropine	S	Unknown		Not Reported
Benzotropine	S	Unknown		Not Reported
Clonazepam	S	Unknown		Not Reported
Clonazepam	S	Unknown		Not Reported
Fluoxetine	S	Unknown		Not Reported
Fluoxetine	S	Unknown		Not Reported
Diphenhydramine	S	Unknown		Not Reported
Azithromycin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13040319	EXPEDITED (15-DAY)		HO	IN-IPCA LABORATORIES LIMITED-IPC201612- 000994		7 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>	
Haemolysis; Methaemoglobinaemia	Chloroquine Phosphate Primaquine			S S				Ipca Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13049391	EXPEDITED (15-DAY)		HO, OT	US-MACLEODS PHARMACEUTICALS US LTD- MAC2016004052			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Amaurosis; Anxiety;	Olanzapine	S	Unknown	2.5 Mg, Qd	Macleods
Areflexia; Catatonia;	Olanzapine	S	Unknown	17.5 Mg, Qd	Macleods
Condition Aggravated;	Fluoxetine	S	Unknown	Unk	Not Reported
Confusional State;	Lorazepam	S	Unknown	Unk	Not Reported
Delusion; Drug Interaction;	Lorazepam	S	Unknown	Unk	Not Reported
Dysphonia; Facial	Diphenhydramine	S	Unknown	Unk	Not Reported
Paralysis; Feeling Guilty;	Clonazepam	S	Unknown	Unk	Not Reported
Hallucination;	Risperidone	S	Unknown	Unk	Not Reported
Hallucination, Auditory;	Benzotropine Mesylate	S	Unknown	Unk	Not Reported
Hallucination, Visual;	Chloroquine	S	Unknown	250 Mg, Once In A Week	Not Reported
Insomnia; Malaise;	Azithromycin	C	Unknown	Unk, Qd	Not Reported
Mydriasis;					
Neuropsychiatric					
Symptoms; Paranoia;					
Persecutory Delusion;					
Suicidal Ideation; Toxic					
Encephalopathy; Toxicity					
To Various Agents					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13056697	EXPEDITED (15-DAY)		LT, OT	US-EDGEMONT-2016EDG00036		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; Autonomic Nervous System	Fluoxetine			S	Unknown			Edgemont
Imbalance; Catatonia;	Chloroquine			S	Unknown	250 Mg, 1x/Week		Not Reported
Delusion; Drug Interaction;	Diphenhydramine			S	Unknown			Not Reported
Encephalopathy; Facial	Risperidone			S	Unknown			Not Reported
Paralysis; Hallucination;	Benzotropine Mesylate			S	Unknown			Not Reported
Suicidal Ideation; Toxicity	Rivastigmine			S	Transdermal			Not Reported
To Various Agents	Rivastigmine			S	Oral	Unk		Not Reported
	Clonazepam			C				Not Reported
	Olanzapine			C		2.5 Mg, 1x/Day		Not Reported
	Olanzapine			C		17.5 Mg, 1x/Day		Not Reported
	Lorazepam			C		Unk, As Needed		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	12547139	EXPEDITED (15-DAY)		DE	JP-IMPAX LABORATORIES, INC- 2016-IPXL-00715		21 YR	Female	TZA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	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>
23-Dec-2016	12547149	EXPEDITED (15-DAY)		DE	JP-IMPAX LABORATORIES, INC- 2016-IPXL-00716		34 YR	Male	TZA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	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>
23-Dec-2016	13060327	EXPEDITED (15-DAY)		DE	US-IMPAX LABORATORIES, INC- 2016-IPXL-02417		1 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Chloroquine Phosphate			S	Oral	300 Mg, One Tablet		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>
26-Dec-2016	13061306	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-046768		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>	
Condition Aggravated;	Clonazepam			S				Accord	
Drug Interaction;	Olanzapine			S				Not Reported	
Hallucination; Toxic	Fluoxetine			S				Not Reported	
Encephalopathy; Toxicity	Lorazepam			S				Not Reported	
To Various Agents	Risperidone			S				Not Reported	
	Benzatropine			S				Not Reported	
	Diphenhydramine			S				Not Reported	
	Chloroquine			S				Not Reported	

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

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>
27-Dec-2016	12547140	EXPEDITED (15-DAY)		DE	DE-IMPAX LABORATORIES, INC- 2016-IPXL-00717		19 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>	
Completed Suicide; Intentional Overdose; Toxicity To Various Agents	Chloroquine Phosphate			S	Oral	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>
27-Dec-2016	12547173	EXPEDITED (15-DAY)		DE, HO	NG-IMPAX LABORATORIES, INC- 2016-IPXL-00721		45 YR	Male	NGA
<u>Preferred Term</u>	<u>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; Drug Abuse; Seizure; Toxicity To Various Agents	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S	Unknown	3000 Mg, Unk		Impax	
	Chloroquine Phosphate			S	Unknown	1500 Mg, 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>
27-Dec-2016	12547174	EXPEDITED (15-DAY)		HO, OT	US-IMPAX LABORATORIES, INC- 2016-IPXL-00720		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Complete; Cardiac Failure Congestive; Restrictive Cardiomyopathy	Chloroquine Phosphate			S	Unknown	200 Mg, Daily		Impax	
	Chloroquine Phosphate			S	Unknown	300 Mg, Daily		Impax	
	Chloroquine Phosphate			S	Unknown	600 Mg, Daily		Impax	
	Torsemide			C	Unknown	Unk		Not Reported	
	Digoxin			C	Unknown	Unk		Not Reported	
	Vitamin E			C	Unknown	Unk		Not Reported	
	Acetaminophen/Hydrocodone			C	Unknown	Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13065593	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201612- 001014		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>	
Chorioretinopathy; Diplopia; Dizziness; Drug Interaction; Toxicity To Various Agents	Chloroquine Phosphate			S				Ipca	
	Mefloquine			S				Not Reported	
	Primaquine			S				Not Reported	
	Omeprazole			S				Not Reported	
	Domperidone			S				Not Reported	
	Chlordiazepoxide/Clidinium Bromide			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-Dec-2016	13066327	EXPEDITED (15-DAY)		OT	PHHY2016US176876		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>	
Drug Interaction	Fluoxetine			S	Unknown			Novartis	
	Chloroquine			S	Unknown	250 Mg, Qw		Not Reported	
	Risperidone			C	Unknown			Not Reported	
	Diphenhydramine			C	Unknown			Not Reported	
	Olanzapine			C	Unknown			Not Reported	
	Lorazepam			C	Unknown			Not Reported	
	Clonazepam			C	Unknown			Not Reported	
	Benzotropine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13066601	EXPEDITED (15-DAY)		DE	DE-IMPAX LABORATORIES, INC- 2016-IPXL-02379		65 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>	
Completed Suicide;	Chloroquine Phosphate			S	Unknown	Unk		Impax	

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Overdose

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	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		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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2016	13068608	EXPEDITED (15-DAY)		HO	US-MYLANLABS- 2016M1057228			Unknown	HND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cinchonism; Condition Aggravated	Diphenhydramine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Rivastigmine			S	Transdermal			Not Reported
	Olanzapine			S	Unknown	Increased From 2.5mg To 17.5mg Daily		Not Reported
	Benzatropine			S	Unknown			Mylan
	Chloroquine			S	Unknown	250mg Weekly		Mylan
	Azithromycin			C	Unknown	Standard Dose		Mylan

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

Lorazepam	C	Unknown	Mylan
Clonazepam	C	Unknown	Mylan
Paliperidone	C	Unknown	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	13073193	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2016AP016196		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>
Condition Aggravated; Toxic Encephalopathy	Fluoxetine Oral Solution Usp			S	Unknown			Apotex
	Clonazepam Tablets Usp			S	Unknown			Apotex
	Olanzapine			S	Unknown	2.5 Mg, Qd		Apotex
	Olanzapine			S	Unknown	17.5 Mg, Qd		Apotex
	Risperidone			S	Unknown			Apotex
	Diphenhydramine			S	Unknown	Unk		Not Reported
	Benzatropine			S	Unknown			Not Reported
	Rivastigmine			S	Transdermal	Unk		Not Reported
	Rivastigmine			S	Oral	Unk		Not Reported
	Lorazepam			S	Unknown	Unk		Not Reported
Chloroquine			S	Unknown	250 Mg, Q.Wk.		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2017	13045198	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/16/0085647		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; Catatonia; Condition Aggravated; Confusional State; Drug Interaction; Dysphonia; Facial Paralysis; Hallucination; Illusion; Insomnia; Mydriasis;	Olanzapine Tablets 2.5 Mg, 5 Mg, 7.5 Mg, 10 Mg			S	Unknown			Not Reported
	Olanzapine Tablets 2.5 Mg, 5 Mg, 7.5 Mg, 10 Mg			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported

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

Paranoia; Persecutory Delusion; Suicidal Ideation; Toxic Encephalopathy; Toxicity To Various Agents	Clonazepam Lorazepam Benztropine Mesylate Chloroquine Azithromycin	S S S S C	Unknown Unknown Unknown Unknown Unknown	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>
05-Jan-2017	13087136	EXPEDITED (15-DAY)		HO, OT	US-ZYDUS-013059		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; Catatonia; Confusional State; Delusional Perception; Dysphonia; Facial Paralysis; Hallucination, Auditory; Hallucination, Visual; Illusion; Paranoia; Persecutory Delusion; Suicidal Ideation	Risperidone Olanzapine Chloroquine Diphenhydramine Fluoxetine Benzatropine/Benzatropine Mesilate Lorazepam Clonazepam			S S S S S S C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Zydu Pharm Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	13089161	NON-EXPEDITED			US-SA-2016SA001650		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Aralen			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2017	13089162	NON-EXPEDITED			US-SA-2016SA043645		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Depression	Aralen	S	Unknown	Not Reported
	Darvon	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2017	13089845	EXPEDITED (15-DAY)		HO	US-TEVA-725459USA		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>
Cinchonism; Condition Aggravated	Diphenhydramine			S	Unknown			Barr
	Fluoxetine			S	Unknown			Barr
	Risperidone			S	Unknown			Actavis
	Rivastigmine			S	Transdermal			Actavis
	Olanzapine			S	Unknown	Increased From 2.5mg To 17.5mg Daily		Teva
	Chloroquine			S	Unknown	250mg Weekly		Not Reported
	Benzatropine			S	Unknown			Not Reported
	Azithromycin			C	Unknown	Standard Dose		Not Reported
	Lorazepam			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Paliperidone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2017	12357049	NON-EXPEDITED		OT	US-ARBOR PHARMACEUTICALS, LLC-US- 2016ARB000016			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>
Hypersensitivity	Erythromycin			S		Unk		Arbor
	Aralen /00001002/			S		Unk		Not Reported
	Aspirin /00002701/			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Quinine			S		Unk		Not Reported

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

Valisone	S	Unk	Not Reported
Benzocaine	S	Unk	Not Reported
Lyrica	C	25 Mg, Tid	Not Reported
Allegra	C	60 Mg, Bid	Not Reported
Bupropion Hcl	C	300 Mg, Qd	Not Reported
Colace	C	100 Mg, Bid	Not Reported
Eliquis	C	5 Mg, Bid	Not Reported
Estradiol	C	Vaginal 2 Mg, Once Every 3 Months	Not Reported
Tylenol Extra Strength	C	1000 Mg, Qid	Not Reported
Flexeril /00428402/	C	10 Mg, Bid	Not Reported
Hyaluronic Acid	C	1 Tbsp Once A Day	Not Reported
Lopressor	C	50 Mg, Bid	Not Reported
Prednisone	C	5 Mg, Qd	Not Reported
Risperdal	C	1 Mg, Qd (Nightly)	Not Reported
Tramadol Hcl	C	50 Mg, Tid	Not Reported
Wellbutrin	C	150 Mg, Qd	Not Reported
Xanax	C	1 Mg, Tid	Not Reported
Zocor	C	20 Mg, Qd (Nightly)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2017	12653086	NON-EXPEDITED			US-EGALET US INC- US-2015EGA000152			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>
Liver Function Test Increased; Weight Increased	Oxycodone Hydrochloride			S		Unk		Egalet
	Enbrel			S		Unk		Not Reported
	Reglan /00041902/			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Xeljanz			S		1 Df, Daily		Not Reported

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Azithromycin	S	Unk	Not Reported
Actemra	S	162 Mg, Qwk	Not Reported
Codeine Sulfate	S	Unk	Not Reported
Chloroquine	S	Unk	Not Reported
Keflex /00145501/	S	Unk	Not Reported
Metamucil /00091301/	C	Unk	Not Reported
Vitamin D /00107901/	C	Unk	Not Reported
Bayer Aspirin	C	81 Mg, Unk	Not Reported
Multivitamin /00097801/	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2017	13131604	EXPEDITED (15-DAY)		HO	GB-IMPAX LABORATORIES, INC- 2017-IPXL-00005		33 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>
Hypomania; Medication Error	Chloroquine Phosphate			S	Unknown	300 Mg, 1 /Week		Impax
	Chloroquine Phosphate			S	Unknown	600 Mg, Taken By Error		Impax
	Chloroquine Phosphate			S	Unknown	300 Mg, Unk		Impax
	Proguanil Hcl			C	Unknown	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>
27-Jan-2017	13157172	EXPEDITED (15-DAY)		HO, OT	US-ALVOGEN-2017- ALVOGEN-091332		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;	Fluoxetine			S				Not Reported
	Lorazepam			S				Not Reported
	Olanzapine			S				Not Reported
	Risperidone			S				Not Reported
	Clonazepam			S				Not Reported
	Diphenhydramine			S				Not Reported
	Chloroquine			S				Not Reported
	Benzatropine Mesilate			S				Not Reported
	Azithromycin			C				Not Reported

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

Toxicity To Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2017	13159713	EXPEDITED (15-DAY)		OT	BR-SA-2017SA013293		39 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>	
Gingival Ulceration;	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
Palatal Ulcer;	Methotrexate			S	Unknown			Not Reported	
Paracoccidioides Infection;	Prednisone			S	Unknown			Not Reported	
Rash Erythematous;	Azithromycin			C				Not Reported	
Stomatitis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2017	13185662	NON-EXPEDITED			US-IMPAX LABORATORIES, INC- 2016-IPXL-01426			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>	
Nausea	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>
10-Feb-2017	13212970	EXPEDITED (15-DAY)		OT	CA-SA-2015SA134263		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Plaquenil			S	Unknown			Not Reported	
Drug Ineffective; Fall;	Arava			S	Oral			Not Reported	
Feeling Abnormal;	Leflunomide			S	Unknown			Not Reported	
Hypoacusis; Nausea;	Methotrexate Sodium			S	Subcutaneous			Not Reported	
Pain; Rheumatoid Arthritis;	Chloroquine			S	Unknown			Not Reported	
Swelling; Weight	Enbrel			S	Unknown			Not Reported	
Decreased	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13156166	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2017PL011330		59 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>	
Interstitial Lung Disease; Leukopenia; Neutropenia; Respiratory Failure	Leflunomide			S	Unknown	100 Mg, Qd, For 3 Days		Novartis	
	Leflunomide			S	Unknown	20 Mg, Qd		Novartis	
	Methotrexate			S	Unknown	20 Mg, Qw		Not Reported	
	Cyclophosphamide			S	Unknown	150 Mg, Qd		Not Reported	
	Prednisone			S	Unknown	For Ra		Not Reported	
	Prednisone			S	Unknown	For Interstitial Pneumonia		Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Arechin			S	Unknown			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2017	13250271	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702- 001097		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Plaquenil			S	Unknown			Concordia	
	Arava			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Methotrexate Sodium			S	Subcutaneous			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2017	13257277	EXPEDITED (15-DAY)		DE	GB-IMPAX LABORATORIES, INC- 2017-IPXL-00350		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>	
Asphyxia; Completed Suicide; Toxicity To Various Agents	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>
21-Feb-2017	13258268	EXPEDITED (15-DAY)		DE, HO	AU-IMPAX LABORATORIES, INC- 2017-IPXL-00348		20 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>	
Accidental Overdose; Bundle Branch Block Right; Diplopia; Hypoaesthesia; Incorrect Dose Administered; Influenza Like Illness; Seizure; Throat Tightness; Toxicity To Various Agents; Ventricular Fibrillation; Ventricular Tachycardia; Viral Myocarditis; Vomiting	Chloroquine Phosphate			S	Unknown	200 Mg, Two Tablets Weekly		Impax	
	Chloroquine Phosphate			S	Unknown	200 Mg, Two Tablets Daily		Impax	
	Chloroquine Phosphate			S	Unknown	200 Mg, 45 Tablets, Single Dose		Impax	
	Dapsone W/Pyrimethamine			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-Feb-2017	13258269	EXPEDITED (15-DAY)		DE, HO	US-IMPAX LABORATORIES, INC- 2017-IPXL-00351		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Coma; Completed Suicide; Hypokalaemia; Intentional Overdose; Lethargy; Vomiting	Chloroquine Phosphate			S	Unknown	Unk		Impax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2017	13258270	EXPEDITED (15-DAY)		DE	GB-IMPAX LABORATORIES, INC- 2017-IPXL-00353		29 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 Arrest; Toxicity To Various Agents	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>
27-Feb-2017	13228925	EXPEDITED (15-DAY)		OT	KR-CONCORDIA PHARMACEUTICALS INC.-GSH201702- 001022		53 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maculopathy; Myopia; Optical Coherence Tomography Abnormal; Retinal Depigmentation; Visual Acuity Tests Abnormal; Visual Field Defect; Visual Impairment	Plaquenil Chloroquine			S S	Unknown Unknown			Concordia Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2017	13274116	EXPEDITED (15-DAY)		OT	SN-SA-2017SA030312			Unknown	SEN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electroencephalogram Abnormal; Histology Abnormal; Myasthenic Syndrome; Neuromyopathy; Toxicity To Various Agents	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13287496	EXPEDITED (15-DAY)		OT	US-IPCA LABORATORIES LIMITED-IPC201702-		59 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fungal Infection; Infective Tenosynovitis	Chloroquine Phosphate Mycophenolate Prednisone			S S S				Ipca Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13295791	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC- 2017-IPXL-00006		15 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose; Catatonia; Drug Screen	Chloroquine Phosphate			S	Unknown	Unk		Impax
False Positive; Substance-Induced Psychotic Disorder; Wrong Product Administered	Chloroquine Phosphate			S		Unk; Resumed		Impax
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C		Unk; Resumed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Mar-2017	13299957	EXPEDITED (15-DAY)		HO, OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-00497		18 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>
Catatonia; Mania	Chloroquine Phosphate			S	Unknown	4 Tablet Of Chloroquine		Impax
	Chloroquine Phosphate			S		2 Tablets After Six Hours Following The Initial Dose		Impax
	Chloroquine Phosphate			S		2 Tablets Daily		Impax
	Paracetamol			C	Unknown	500 Mg, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2017	13299958	EXPEDITED (15-DAY)		HO	IN-IMPAX LABORATORIES, INC- 2017-IPXL-00496		18 YR	Male	IND

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar I Disorder; Extrapyramidal Disorder; Mania	Chloroquine Phosphate			S	Unknown	04 Tablets Of 600 Mg		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>
06-Mar-2017	13299979	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-00498		38 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>	
Mania	Chloroquine Phosphate			S	Unknown	150 Mg, 3 Tablets In Divided Dosage		Impax	
	Aspirin			C	Oral	300 Mg, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2017	13299980	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-00499		15 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>	
Mania	Chloroquine Phosphate			S	Unknown	6 Tablets For A Day In Two Divided Doses		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>
06-Mar-2017	13299981	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-00500		30 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>	
Mania	Chloroquine Phosphate			S	Unknown	Four Tablets Stat And One B.I.D. For Four Days		Impax	
	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>
06-Mar-2017	13299992	EXPEDITED (15-DAY)		HO, OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-00495		17 YR	Female	IND

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Headache; Insomnia; Mania; Suicidal Ideation	Chloroquine Phosphate			S	Intramuscular	5 MI (40 Mg/MI)		Impax	
	Chloroquine Phosphate			S	Oral	150 Mg Of Base In Two Divided Dosages		Impax	
	Paracetamol			C	Oral	500 Mg, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13333823	EXPEDITED (15-DAY)		HO	ES-SA-2017SA037243		14 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Dizziness; Headache; Intentional Overdose; Overdose; Rash	Chloroquine Phosphate			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13378263	EXPEDITED (15-DAY)		HO	FR-IPCA LABORATORIES LIMITED-IPC201703-000325		32 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>	
Cardiogenic Shock; Cardiotoxicity; Hyperlactacidaemia; Hypokalaemia; Intentional Overdose; Toxicity To Various Agents	Chloroquine Phosphate			S		Ingested Dose Of 9.5 G		Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2017	13420151	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP009425		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infective Tenosynovitis	Mycophenolate Mofetil			S	Unknown	Unk		Apotex	

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		Prednisone		S	Unknown	Unk			Not Reported
		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>
17-Apr-2017	13287119	EXPEDITED (15-DAY)		OT	CA-IMPAX LABORATORIES, INC- 2017-IPXL-00493		23 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>	
Anxiety; Bradycardia; Bradypnoea; Condition Aggravated; Depression; Fatigue; Hallucination; Paraesthesia; Paranoia; Paresis; Suicidal Ideation; Tachycardia; Tachypnoea; Tinnitus; Vertigo	Chloroquine Phosphate Mefloquine			S S	Oral Unknown	300 Mg, Unk 228 Mg, Weekly		Impax Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2017	13489204	EXPEDITED (15-DAY)		HO, OT	BR-SA-2017SA072928		73 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>	
Biopsy Skin Abnormal; Facial Pain; Mucocutaneous Leishmaniasis; Nasal Crusting; Nodule; Parasite Dna Test Positive; Rash Erythematous; Ulcer	Chloroquine (Salt Not Specified) Methotrexate Prednisone Golimumab			S S S S	Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2017	13495732	EXPEDITED (15-DAY)		HO, OT	BR-SA-2017SA072988		51 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>	
Cutaneous Leishmaniasis; Oedema; Pain; Pyrexia; Scar; Skin Ulcer; Skin	Chloroquine (Salt Not Specified) Methotrexate			S S	Oral Intramuscular			Not Reported Not Reported	

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Ulcer	Prednisone	S	Oral	Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2017	13499693	EXPEDITED (15-DAY)		OT	US-SA-2017SA077165		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Retinal Toxicity; Skin Hyperpigmentation	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Minocycline Hydrochloride			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Allopurinol			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Thalidomide			S	Unknown			Not Reported
	Adalimumab			S	Unknown			Not Reported
	Cyclosporine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13164020	EXPEDITED (15-DAY)		HO	US-LPDUSPRD-20170049		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>
Condition Aggravated	Olanzapine For Injection (0517-0955-01)			S	Unknown	Unknown		Luitpold
	Azithromycin			C	Unknown			Not Reported
	Benzotropine			S		Unknown		Not Reported
	Chloroquine			S	Unknown	250 Mg		Not Reported
	Diphenhydramine			S	Unknown	Unknown		Not Reported

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Lorazepam	C	Unknown	Not Reported
Risperidone	C		Not Reported
Fluoxetine	C	Unknown	Not Reported
Clonazepam	C	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13483959	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-33075		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection; Pain; Skin Discolouration; Swelling; Tenosynovitis; Wheezing	Prednisone			S	Unknown			Aurobindo	
	Mycophenolate			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>
09-May-2017	13512371	EXPEDITED (15-DAY)		DE	ALCN2017RU003088		30 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents	Tropicamide			S	Unknown	Unk		Novartis	
	Morphine			S	Unknown	Unk		Not Reported	
	Codeine Phosphate			S	Unknown	Unk		Not Reported	
	Phenobarbital			S	Unknown	Unk		Not Reported	
	Alcohol			S	Unknown	Unk		Not Reported	
	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>
22-May-2017	13512083	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201705-002731			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Retinal Toxicity; Skin	Hydroxychloroquine			S	Unknown			Concordia	

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

Hyperpigmentation	Minocycline Hydrochloride	S	Unknown	Not Reported
	Chloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Allopurinol	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Thalidomide	S	Unknown	Not Reported
	Adalimumab	S	Unknown	Not Reported
	Cyclosporine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13497131	EXPEDITED (15-DAY)		HO, OT	BR-PFIZER INC-2017183729		51 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>
Cutaneous Leishmaniasis	Methotrexate Sodium			S	Intramuscular	25 Mg, Weekly		Pfizer
	Prednisone			S	Oral	5 Mg, Daily		Not Reported
	Chloroquine			S	Oral	400 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13603428	EXPEDITED (15-DAY)		OT	ES-IMPAX LABORATORIES, INC-2017-IPXL-01531		57 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acquired Pigmented Retinopathy; Macular Oedema	Chloroquine Phosphate			S	Unknown	Unk		Impax

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13497173	EXPEDITED (15-DAY)		HO, OT	BR-PFIZER INC-2017183739		73 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>	
Mucocutaneous Leishmaniasis	Methotrexate Sodium			S		7.5 Mg, Weekly		Pfizer	
	Prednisone			S		6 Mg, Weekly		Not Reported	
	Chloroquine			S		100 Mg, Weekly		Not Reported	
	Golimumab			S		50 Mg, Monthly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13603885	EXPEDITED (15-DAY)		OT	ES-IPCA LABORATORIES LIMITED-IPC-2017-WO-000593			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acquired Pigmented Retinopathy; Macular Oedema	Chloroquine			S				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>
06-Jun-2017	13347969	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-136065		35 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>	
Exposure During Pregnancy; Hypothyroidism; Live Birth	Methotrexate			S	Unknown	25 Mg, 1/Week		Not Reported	
	Prednisone			S	Oral	10 Mg, Daily		Mutual	
	Chroloquine Diphosphate			S	Unknown	4 Mg/Kg, Daily		Not Reported	
	Azathioprine			S	Unknown	3 Mg/Kg, 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-2017	13641248	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS		55 YR	Female	CAN

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INC.-GSH201706-003442

<u>Preferred Term</u>	<u>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	Plaquenil Tablet			S	Oral			Concordia
Aggravated; Diverticulitis;	Methotrexate			S	Unknown			Not Reported
H1n1 Influenza; Hepatic	Chloroquine			S	Unknown			Not Reported
Enzyme Increased;	Belimumab			S	Unknown			Not Reported
Hepatomegaly;	Belimumab			S				Not Reported
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>
12-Jun-2017	13644227	EXPEDITED (15-DAY)		HO, OT	US-ALLERGAN-1724028US		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;	Fluoxetine Hcl Unk			S	Oral			Allergan
Areflexia; Catatonia;	Chloroquine			S	Oral	250 Mg, Q Week		Not Reported
Confusional State;	Olanzapine			S	Oral	2.5 Mg, Qd		Not Reported
Delusion; Drug Interaction;	Olanzapine			S	Oral	17.5 Mg, Qd		Not Reported
Dysphonia;	Lorazepam			S	Oral	Unk		Not Reported
Encephalopathy; Facial	Risperidone			S	Oral			Not Reported
Paralysis; Feeling Guilty;	Benzotropine Mesylate			S				Not Reported
Hallucination; Insomnia;	Diphenhydramine			S	Oral			Not Reported
Mydriasis; Off Label Use;	Clonazepam			S	Oral			Not Reported
Paranoia; Persecutory	Azithromycin			C	Unknown	Unk		Not Reported
Delusion; Suicidal								
Ideation; Toxicity To								
Various Agents								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13204204	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA114805		61 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Arthralgia; Arthralgia;	Plaquenil	S	Oral		Not Reported
Arthropathy; Arthropathy;	Arava	S	Oral		Not Reported
Bone Pain; Diarrhoea;	Methotrexate Sodium	S	Oral		Not Reported
Gait Disturbance;	Sulfasalazine	S	Oral		Not Reported
Hypoaesthesia; Malaise;	Remicade	S	Unknown	Form: Powder For Solution	Not Reported
Pain; Post Procedural				Intravenous	
Complication; Sensory	Chloroquine	S	Unknown		Not Reported
Loss; Swelling;	Xeljanz	C	Oral		Not Reported
Therapeutic Product Effect					
Incomplete; Thrombosis;					
Thrombosis; Unevaluable					
Event					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2017	13215699	EXPEDITED (15-DAY)		HO, OT	CA-SA-2015SA114798		60 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy;	Plaquenil			S	Oral			Not Reported
Diarrhoea; Drug	Arava			S	Unknown			Not Reported
Intolerance;	Chloroquine			S	Unknown			Not Reported
Hypoaesthesia; Pain; Post	Methotrexate Sodium			S	Oral			Not Reported
Procedural Complication;	Remicade			S	Unknown			Not Reported
Swelling; Therapeutic	Sulfasalazine			S	Oral			Not Reported
Product Effect Incomplete;	Xeljanz			C	Oral			Not Reported
Thrombosis								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13677740	EXPEDITED (15-DAY)		HO, OT	US-TORRENT-00003119		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;	Clonazepam			S				Unknown
Areflexia; Condition	Risperidone			S				Unknown
Aggravated; Drug	Lorazepam			S				Unknown
Interaction; Facial	Diphenhydramine			S				Unknown
Paralysis; Hallucination;	Olanzapine			S				Unknown
Insomnia; Mydriasis;	Chloroquine			S				Unknown

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Paranoia; Toxic	Benzotropine Mesylate	S	Unknown
Encephalopathy; Toxicity	Azithromycin	C	Unknown
To Various Agents;	Fluoxetine	S	Unknown
Toxicity To Various Agents			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2017	13688595	EXPEDITED (15-DAY)		OT	HU-ROCHE-1954571		59 YR	Female	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>
Carpal Tunnel Syndrome;	Tocilizumab			S	Intravenous (not			Not Reported
Granulocytopenia;					otherwise specified)			
Leukopenia; Monocytosis	Tocilizumab			S	Intravenous (not			Not Reported
					otherwise specified)			
	Tocilizumab			S	Intravenous (not			Not Reported
					otherwise specified)			
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Chloroquina			S	Oral			Not Reported
	Chloroquina			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13516275	EXPEDITED (15-DAY)		HO, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-139735		51 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>
Cutaneous Leishmaniasis	Prednisone			S	Oral	5 Mg, Daily		Mutual
	Chloroquine			S	Oral	400 Mg, Daily		Not Reported
	Methotrexate			S	Intramuscular			Not Reported

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13516281	EXPEDITED (15-DAY)		HO, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-139736		73 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>	
Mucocutaneous Leishmaniasis	Methotrexate			S	Unknown	7.5 Mg, 1/Week		Not Reported	
	Prednisone			S	Unknown	6 Mg, 1/Week		Mutual	
	Chloroquine			S	Unknown	100 Mg, 1/Week		Not Reported	
	Golimumab			C	Unknown	50 Mg, Monthly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13248248	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-E2B_00008020		61 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia; Arthropathy; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Malaise; Pain; Post Procedural Complication; Sensory Loss; Swelling; Therapeutic Product Effect Incomplete; Thrombosis; Thrombosis; Unevaluable Event	Plaquenil Tablet			S	Oral			Concordia	
	Arava			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Sulfasalazine			S	Oral			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Xeljanz			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13701838	EXPEDITED (15-DAY)		HO	BR-MYLANLABS- 2017M1038547			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mucocutaneous Leishmaniasis;	Methotrexate			S	Unknown			Not Reported	

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Nephropathy Toxic	Prednisone	S	Unknown	35mg/Kg; Later (Following Adr), Received A Cumulative Dose Of 2500mg	Not Reported
	Chloroquine	S	Unknown		Mylan
	Golimumab	S	Unknown		Mylan
	Amphotericin B Lipid Complex	S	Other		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>
30-Jun-2017	13047787	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2016-031663		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; Toxicity To Various Agents	Lorazepam			S	Unknown			Not Reported	
	Clonazepam			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Benzotropine Mesylate			S	Unknown			Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			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>
30-Jun-2017	13250616	EXPEDITED (15-DAY)		HO, OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702-001195		60 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Diarrhoea; Drug Intolerance; Hypoaesthesia; Pain; Post	Plaquenil Tablet			S	Oral			Concordia	
	Arava			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	

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Procedural Complication; Swelling; Therapeutic Product Effect Incomplete; Thrombosis	Methotrexate Sodium	S	Oral	Not Reported
	Remicade	S	Unknown	Not Reported
	Sulfasalazine	S	Oral	Not Reported
	Xeljanz	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13031574	EXPEDITED (15-DAY)		HO, OT	US-SA-2016SA224095		16 YR	Female	HND

<u>Preferred Term</u>	<u>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; Confusional State; Drug Interaction; Facial Paralysis; Hallucination; Insomnia; Mydriasis; Paranoia; Toxic Encephalopathy; Toxicity To Various Agents; Toxicity To Various Agents	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Diphenhydramine		Y	S	Unknown			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Clonazepam			S	Unknown			Not Reported
	Olanzapine			S	Unknown			Not Reported
	Olanzapine			S				Not Reported
	Olanzapine			S				Not Reported
	Benzatropine Mesilate			S	Unknown			Not Reported
	Azithromycin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13724540	EXPEDITED (15-DAY)		HO	BR-TEVA-783660ROM		51 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>
Cutaneous Leishmaniasis; Infection Reactivation	Methotrexate			S	Intramuscular			Barr
	Prednisone			S	Oral	5 Milligram Daily;		Not Reported
	Chloroquine			S	Oral	400 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13724573	EXPEDITED (15-DAY)		HO	BR-TEVA-783661ROM		73 YR	Female	BRA

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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>	
Infection Reactivation; Mucocutaneous Leishmaniasis; Nephropathy Toxic	Methotrexate			S	Unknown			Barr	
	Amphotericin B Liposomal			S	Other	35mg/Kg; Later (Following Adr), Received A Cumulative Dose Of 2500mg		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Golimumab			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13724708	EXPEDITED (15-DAY)		OT	BR-FRESENIUS KABI- FK201705820		73 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>	
Mucocutaneous Leishmaniasis	Methotrexate (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Prednisone			S				Not Reported	
	Chloroquine			S				Not Reported	
	Golimumab			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13724709	EXPEDITED (15-DAY)		OT	BR-FRESENIUS KABI- FK201705812		51 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>	
Cutaneous Leishmaniasis	Methotrexate (Manufacturer Unknown)			S	Intramuscular			Fresenius Medical Care	
	Prednisone			S	Oral			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>
07-Jul-2017	13059485	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2016AP015784		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Apo-Leflunomide	S	Unknown	20 Mg, Qd	Apotex
	Apo-Sulfasalazie	S	Unknown	1 G, Bid	Not Reported
	Chloroquine	S	Unknown	250 Mg, Qd	Not Reported
	Arava	S	Oral	20 Mg, Qd	Not Reported
	Enbrel	S	Unknown	20 Mg, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Mg, Q.Wk.	Not Reported
	Plaquenil /00072602/	S	Unknown	250 Mg, Qd	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2017	13734330	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001310			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>	
Corneal Defect	Metformin			S		500 Mg, Unk		Ipca	
	Chloroquine Phosphate Tablets			S		500 Mg, 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>
09-Jul-2017	13734399	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001361			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>	
Arthropathy	Metformin			S		500 Mg, Unk		Ipca	
	Chloroquine Phosphate Tablet			S		500 Mg, 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>
09-Jul-2017	13734427	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001400			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>	

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Menorrhagia	Metformin		S			500 Mg, Unk		Ipca	
	Chloroquine Phosphate Tablet		S			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>
10-Jul-2017	13735342	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001489			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>	
Depression	Metformin			S		1000 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, Unk		Ipca	
	Artemether Injection			S		80 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-Jul-2017	13735617	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001498			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>	
Aggression; Violence- Related Symptom	Metformin			S		1000 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, Unk		Ipca	
	Primaquine 45 Mg Tablets			S		45 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>
11-Jul-2017	13739856	EXPEDITED (15-DAY)		HO, OT	PL-APOTEX- 2017AP013914		40 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>	
Drug Ineffective; Haemophagocytic Lymphohistiocytosis	Cyclosporine			S	Unknown			Apotex	
	Prednisone			S	Unknown	40–30 Mg		Not Reported	
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported	
	Azathioprine			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13740047	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001533			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>	
Musculoskeletal Stiffness; Rheumatoid Arthritis	Metformin			S		1000 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, 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>
11-Jul-2017	13740085	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001537			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>	
Tendinous Contracture	Metformin			S		1000 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, 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>
11-Jul-2017	13740348	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001562			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>	
Condition Aggravated; Neuropathy Peripheral	Metformin			S		500 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, 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>
11-Jul-2017	13740509	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001576			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>	

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Intervertebral Disc Protrusion	Metformin		S			500 Mg, Unk		Ipca	
	Chloroquine		S					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>
12-Jul-2017	13744079	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001538			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>	
Psychiatric Decompensation	Metformin			S		1000 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13744205	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN- 001771			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>	
Hand Deformity	Metformin			S		500 Mg, Unk		Ipca	
	Chloroquine			S		500 Mg, 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>
21-Jul-2017	13778642	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED- 2017SP005905			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>	
Histoplasmosis; Infective Tenosynovitis; Pain; Skin Discolouration; Swelling; Wheezing	Mycophenolate Mofetil			S	Unknown	Unk, Unknown		Strides	
	Prednisolone			S	Unknown	Unk, Unknown		Not Reported	
	Chloroquine			S	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2017	13525676	EXPEDITED (15-DAY)		DE, HO	CO-ROCHE-1902196		17 YR	Female	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Epistaxis; Tuberculosis	Actemra	S	Subcutaneous	Not Reported
	Prednisolone	S	Oral	Not Reported
	Chloroquine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	12831565	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2016137018		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Enbrel			S	Unknown	Unk		Amgen	
Anxiety; Arthralgia; Drug	Anaprox			S	Unknown	Unk		Not Reported	
Ineffective; Eye Disorder;	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
Hand Deformity; Joint	Aralen			S	Unknown	Unk		Not Reported	
Contracture; Joint	Sulfasalazine			S	Unknown	Unk		Not Reported	
Swelling; Knee	Simponi			S	Subcutaneous	Unk		Not Reported	
Arthroplasty; Malaise;	Humira			C	Unknown	Unk		Not Reported	
Musculoskeletal Pain;									
Pain In Extremity;									
Peripheral Swelling;									
Therapeutic Product Effect									
Decreased; Throat									
Irritation; Treatment									
Failure									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13819665	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016466626		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Enbrel			S		Unk		Pfizer	
Drug Ineffective;	Methotrexate Sodium			S	Subcutaneous	12.5 Mg, Weekly		Unknown	
Dyspnoea; Gait	Sulfasalazine			S	Unknown	Unk		Pfizer	
Disturbance; Latent	Aralen			S		Unk		Not Reported	
Tuberculosis; Localised	Gold			S	Unknown	Unk		Not Reported	
Infection; Nausea; Nodule;	Humira			S	Unknown	Unk		Not Reported	
Pain In Extremity;									
Peripheral Swelling									

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

Simponi			S	Unknown	Unk	Not Reported					
Irbesartan			C		150 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>		
08-Aug-2017	13845320	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-02332		40 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>			
Depression Suicidal	Chloroquine Phosphate			S	Oral	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>		
08-Aug-2017	13845349	EXPEDITED (15-DAY)		OT	IN-IMPAX LABORATORIES, INC- 2017-IPXL-02333		32 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>			
Depressed Mood; Paranoia; Psychomotor Retardation; Suicidal Ideation	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>		
11-Aug-2017	13858019	EXPEDITED (15-DAY)			PL-ALKEM LABORATORIES LIMITED-PL-ALKEM- 001656		44 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>			
Central Nervous System Lymphoma; Necrotising Herpetic Retinopathy	Mycophenolate Mofetil			S	Intravenous (not otherwise specified)	Previously Received Oral Prednisone (40 Mg/Day)		Alkem	Not Reported		
	Methylprednisolone			S				Not Reported			
	Arechin			S	Intravenous (not otherwise specified)			Not Reported	Not Reported		
	Prednisone			S				Not Reported			
		Mycophenolic Acid			S			Intravenous (not otherwise specified)			Not Reported
	Mycophenolic Acid			S	Not Reported						

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

Mycophenolic Acid

S

Previously Received Oral
Prednisone (40 Mg/Day)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2017	13887875	EXPEDITED (15-DAY)		OT	AT-MYLANLABS- 2017M1051339			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>
Phospholipidosis	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Mylan
	Azathioprine			C	Unknown			Mylan
	Mycophenolate Mofetil			C	Unknown			Mylan
	Rituximab			C	Unknown			Mylan
	Cyclophosphamide			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13042662	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC- 2016582529		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; Dysphonia; Facial Paralysis; Hallucination; Insomnia; Mydriasis; Paranoia; Toxic Encephalopathy; Toxicity To Various Agents	Diphenhydramine Hcl			S		Unk		Unknown
	Lorazepam			S		Unk, As Needed		Pfizer
	Lorazepam			S				Pfizer
	Olanzapine			S		2.5 Mg, Daily		Not Reported
	Olanzapine			S		17.5 Mg, Daily		Not Reported
	Fluoxetine			S		Unk		Not Reported
	Risperidone			S		Unk		Not Reported
	Benzotropine Mesylate			S		Unk		Not Reported
	Clonazepam			S		Unk		Not Reported
	Chloroquine			S		250 Mg, Weekly		Not Reported
	Azithromycin			C		Unk (Standard Dose)		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13065918	EXPEDITED (15-DAY)		DE	DE-IMPAX LABORATORIES, INC- 2016-IPXL-02415		36 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents; Victim Of Homicide	Chloroquine Phosphate			S	Unknown	10-15 Tablets, 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>
22-Aug-2017	13065920	EXPEDITED (15-DAY)		DE, HO	DE-IMPAX LABORATORIES, INC- 2016-IPXL-02414		13 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block First Degree; Brain Injury; Cardiac Arrest; Completed Suicide; Intentional Overdose; Loss Of Consciousness; Myoclonus; Vomiting	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>
23-Aug-2017	13897378	EXPEDITED (15-DAY)		DE	DE-IMPAX LABORATORIES, INC- 2017-IPXL-02451		53 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>	
Circulatory Collapse; Completed Suicide; Intentional Overdose	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				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>
23-Aug-2017	13897559	EXPEDITED (15-DAY)		DE	DE-IMPAX LABORATORIES, INC- 2017-IPXL-02454		38 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Cerebrovascular Accident; General Physical Health Deterioration; Paralysis; Toxicity To Various Agents		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>
23-Aug-2017	13899787	EXPEDITED (15-DAY)		DE	DE-IMPAX LABORATORIES, INC- 2017-IPXL-02453		30 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>	
Blood Pressure Increased; Completed Suicide; Intentional Overdose	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				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>
28-Aug-2017	13053843	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-129855		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; Toxicity To Various Agents	Clonazepam			S	Unknown			Sun	
	Diphenhydramine			S	Unknown			Sun	
	Fluoxetine			S	Unknown			Sun	
	Lorazepam			S	Unknown			Sun	
	Olanzapine			S	Unknown	2.5 Mg, Daily		Sun	
	Olanzapine			S	Unknown	17.5 Mg, Daily		Sun	
	Risperidone			S	Unknown			Ranbaxy	
	Benzotropine Mesylate			S	Unknown			Not Reported	
	Chloroquine			S	Unknown	250 Mg, 1/Week		Not Reported	
Azithromycin			C	Unknown	Unk, Daily		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13909934	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.- 2017US14982			Unknown	USA

FDA Adverse Event Reporting System

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Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis; Anxiety; Areflexia; Condition Aggravated; Drug Interaction; Facial Paralysis; Hallucination; Insomnia; Mydriasis; Paranoia; Toxic Encephalopathy; Toxicity To Various Agents; Toxicity To Various Agents	Olanzapine			S	Unknown	2.5 Mg, Bid		Invagen
	Olanzapine			S	Unknown	17.5 Mg, Qd		Invagen
	Fluoxetine			S		Unk		Cipla
	Lorazepam			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Cipla
	Benzotropine			S	Unknown	Unk		Invagen
	Diphenhydramine			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported
	Clonazepam			S	Unknown	Unk		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-Sep-2017	13890834	EXPEDITED (15-DAY)		OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201708- 004772		22 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>
Chronic Cutaneous Lupus Erythematosus; Condition Aggravated; Drug Ineffective; Herpes Zoster; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia
	Prednisone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aspirin			S				Not Reported
	Tacrolimus			S	Topical			Not Reported
	Ilomedin			S				Not Reported
	Belimumab			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13940786	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2017381158		55 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>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intervertebral Disc Degeneration;	Methotrexate Sodium	S	15 Mg, Weekly	Pfizer
Rheumatoid Arthritis;	Salazopyrine	S	1 G, 2x/Day	Pfizer
Spinal Osteoarthritis	Nivaquine /00001001/	S	200 Mg, Daily	Not Reported
	Folic Acid	C	5 Mg, Daily	Not Reported
	Coxflam	C	15 Mg, Daily	Not Reported
	Prednisone	C	10 Mg Daily, 4x 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>
07-Sep-2017	13942244	EXPEDITED (15-DAY)		HO, OT	US-HERITAGE PHARMACEUTICALS- 2017HTG00253		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;	Fluoxetine			S	Unknown			Heritage
Areflexia; Catatonia;	Chloroquine			S	Unknown	250 Mg, 1x/Week		Not Reported
Confusional State;	Diphenhydramine			S	Unknown			Not Reported
Delusion; Dysphonia;	Olanzapine			S	Unknown	2.5 Mg, 1x/Day		Not Reported
Facial Paralysis; Fatigue;	Olanzapine			S		17.5 Mg, 1x/Day		Not Reported
Hallucination, Auditory;	Lorazepam			S	Unknown			Not Reported
Hallucination, Visual;	Lorazepam			S				Not Reported
Insomnia; Mydriasis;	Risperidone			S	Unknown			Not Reported
Paranoia; Persecutory	Benzotropine			S	Unknown			Not Reported
Delusion; Suicidal	Clonazepam			S	Unknown			Not Reported
Ideation; Toxic	Azithromycin			C	Unknown	Unk, 1x/Day X 5 Days		Not Reported
Encephalopathy; Toxicity								
To Various Agents								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2017	13949372	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA163948		59 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>
Aphthous Ulcer; Eye	Arava			S	Oral			Not Reported
Disorder; Headache;	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
Hepatic Fibrosis; Nausea;								
Rash								

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	Humira	S	Unknown	2w		Not Reported
	Methotrexate	S	Unknown			Not Reported
	Salazopyrin	C				Not Reported
	Enbrel	C	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13995032	NON-EXPEDITED			US-ORION CORPORATION ORION PHARMA-TREX2017- 1757			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Treatment Failure	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Dapsone			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	13985086	EXPEDITED (15-DAY)		DE	IN-CONCORDIA PHARMACEUTICALS INC.-GSH201709- 005270		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>
Meningoencephalitis Amoebic	Prednisolone			S				Concordia
	Dexamethasone			S				Not Reported
	Pulse Steroids			S				Not Reported
	Chloroquine			S				Not Reported
	Methotrexate			S		At Admission		Not Reported
	Ceftriaxone			S				Not Reported
	Phenytoin			C				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14035288	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA177258		50 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>	
Cutaneous Vasculitis; Respiratory Tract Infection; Rheumatoid Arthritis; Spondylitis	Arava			S	Oral			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Enbrel			C	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14072221	EXPEDITED (15-DAY)		OT	AT-IPCA LABORATORIES LIMITED-IPC-2017-AT- 003240		63 YR	Male	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>	
Retinal Haemorrhage	Chloroquine			S				Ipca	
	Methylprednisolone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14076936	EXPEDITED (15-DAY)		DS	ZA-BAXTER- 2017BAX034829		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>	
Gastroesophageal Reflux Disease; Hypertension; Periarthritis; Physical Disability	Endoxan Vial 1g			S	Unknown			Baxter	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate			S	Unknown	Triple Dmards		Not Reported	
	Chloroquine			S	Unknown	Triple Dmards		Not Reported	
	Arava			S	Unknown	Triple Dmards		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14084785	EXPEDITED (15-DAY)			ZA-SA-2017SA173785			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>	
Abnormal Product Of Conception; Drug Ineffective; Exposure During Pregnancy; Therapeutic Response Decreased	Arava			S	Oral			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Oral			Not Reported	
	Zidovudine			S	Oral			Not Reported	
	Glucophage			C				Not Reported	
	Omeprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14108411	EXPEDITED (15-DAY)		OT	ZA-IMPAX LABORATORIES, INC-2017-IPXL-02903		11 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>	
Product Use In Unapproved Indication; Systemic Lupus Erythematosus; Treatment Noncompliance	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				Impax	
	Prednisone			S	Unknown	Unk		Not Reported	
	Azathioprine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14108487	EXPEDITED (15-DAY)		OT	ZA-IMPAX LABORATORIES, INC-2017-IPXL-02904		16 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>	
Hypertension; Product Use In Unapproved Indication; Systemic Lupus Erythematosus	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				Impax	
	Prednisone			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14121836	EXPEDITED (15-DAY)		HO	ZA-SA-2017SA201271		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>	
Bronchitis; Encephalitis; Herpes Zoster; Hypoaesthesia; Immune System Disorder	Arava			S	Oral			Not Reported	
	Plasmoquine			S	Unknown			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14121840	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA201262		69 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; Hypertension; Spinal Fusion Surgery	Arava			S	Oral			Not Reported	
	Chloroquine (Salt Not Specified)			S	Oral			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>
26-Oct-2017	14132148	EXPEDITED (15-DAY)		DS	ZA-SA-2017SA201264			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>	
Deformity; Depression; Drug Ineffective; Dyslipidaemia; Impaired Work Ability; Insulin Resistance	Arava			S	Oral			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Cyclophosphamide			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>
27-Oct-2017	14135140	EXPEDITED (15-DAY)		HO	ZA-SA-2017SA206859		50 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>	

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Drug Resistance; Hospitalisation	Chloroquine (Salt Not Specified)	S	Unknown	Not Reported
	Arava	S	Oral	Not Reported
	Methotrexate	S	Subcutaneous	Not Reported
	Salazopyrin	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Lexamil	C	Unknown	Not Reported
	Librax	C	Unknown	Not Reported
	Amitriptyline	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14135180	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA207520		57 YR	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>
Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Altosec			C	Unknown			Not Reported
	Euthyrox			C	Unknown			Not Reported
	Cipramil [Citalopram Hydrochloride]			C	Unknown			Not Reported
	Aspavor			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Oct-2017	14147666	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA210381		45 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>
Drug Tolerance Decreased; Hypertension; Impaired Work Ability; Maculopathy; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Arava			S	Oral			Not Reported
	Azt			S	Unknown			Not Reported

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	Methotrexate	S	Unknown	Not Reported
	Lanzor	C	Unknown	Not Reported
	Vesicare	C	Unknown	Not Reported
	Activelle	C	Unknown	Not Reported
	Enbrel	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	12969826	EXPEDITED (15-DAY)		DE, DS, HO, OT	PL-SA-2016SA207852		44 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>
Blindness; Central Nervous System Lymphoma; Headache; Magnetic Resonance Imaging Brain Abnormal; Necrotising Herpetic Retinopathy; Off Label Use; Optic Neuritis; Retinal Oedema; Varicella Virus Test Positive; Varicella Zoster Virus Infection; Visual Acuity Reduced; Visual Impairment	Mycophenolate Mofetil			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Arechin			S	Unknown			Not Reported
	Arechin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2017	14149125	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2017465678			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

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2017	14149249	EXPEDITED (15-DAY)		OT	BR-TEVA-820280ROM		54 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Tuberculosis	Methotrexate			S	Unknown			Barr	
	Leflunomide			S	Unknown			Not Reported	
	Sulfasalazine			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>
07-Nov-2017	14166023	EXPEDITED (15-DAY)		HO	ZA-SA-2017SA211512		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>	
Pneumocystis Jirovecii Pneumonia; Unevaluable Event	Leflunomide			S	Unknown			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Euthyrox			C	Unknown			Not Reported	
	Asthavent			C	Unknown			Not Reported	
	Verapamil - Slow Release			C	Unknown			Not Reported	
	Bactrim			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2017	14143983	EXPEDITED (15-DAY)		HO	HU-UCBSA-2017042997			Female	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>	
Calcinosis; Dizziness; Genitourinary Tract Infection; Headache;	Cimzia			S		200 Mg, Ev 2 Weeks(Qow)		Ucb	
	Delagil			S		Unk		Not Reported	

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Hiatus Hernia; Paraesthesia; Systemic Lupus Erythematosus	Delagil	S	Increased To 2x1 Tablet	Not Reported
	Delagil	S	Returned To 1x1 Tablet	Not Reported
	Medrol	C	64 Mg, Ev 2 Days (Qod)	Not Reported
	Calcium	C		Not Reported
	Vitamin D3	C		Not Reported
	Doxazosin Mesilate	C	4 Mg 1 Tablet In The Evening	Not Reported
	Hydrochlorothiazide W/Valsartan	C	160mg/25mg 1 Tablet In The Morning	Not Reported
	Tenaxum	C	1 Mg 2x1	Not Reported
	Lecalpin	C	10 Mg 2x1	Not Reported
	Pretanix	C	1.5 Mg 1 Tablet At Noon	Not Reported
	Talliton	C		Not Reported
	Furosemid	C		Not Reported
	Kalium-R	C		Not Reported
	Leflunomid	C		Not Reported
	Salazopyrin	C		Not Reported
	Pantoprazol	C		Not Reported
	Atorva	C		Not Reported
	Zolpidem	C		Not Reported
	Ferrous Sulfate W/Folic Acid	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14184404	EXPEDITED (15-DAY)		HO, OT	ZA-SA-2017SA218184			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>
Deformity; Depression; Peptic Ulcer; Rheumatoid Arthritis; Treatment Failure; Weight Bearing Difficulty	Arava			S	Oral			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14194666	EXPEDITED (15-DAY)		HO, OT	PL-APOTEX-2017AP021137		44 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>	
Central Nervous System Lymphoma; Necrotising Herpetic Retinopathy; Varicella Zoster Virus Infection	Mycophenolate			S	Unknown	2 G Per Day		Apotex	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Arechin			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	20 Mg, Per Day		Not Reported	
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg Per Day		Not Reported	
	Azathioprine /00001502/			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2017	14212639	EXPEDITED (15-DAY)		HO	US-INGENUS PHARMACEUTICALS NJ, LLC-ING201711-00056		19 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>	
Chromaturia; Conjunctival Pallor; Haemolytic Anaemia; Jaundice; Pallor; Splenomegaly; Syncope	Primaquine Phosphate			S				Ingenus	
	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>
22-Nov-2017	14214300	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA225591		21 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>	
Cachexia; Gastroesophageal Reflux Disease; Hypersensitivity; Therapeutic Response Decreased	Plasmoquine			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	

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Enbrel			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2017	14220687	EXPEDITED (15-DAY)		DS	ZA-SA-2017SA228122			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 Work Ability; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Isoniazid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	13692740	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201706- 003794		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Plaquenil Tablet			S	Oral			Concordia	
	Arava			S	Oral			Not Reported	
	Leflunomide			S	Oral			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Subcutaneous			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14227501	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA233460			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	Chloroquine (Salt Not Specified)			S	Unknown	Frequency: 200mg 5 Per		Not Reported	

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

					Week				
	Arava		S	Oral					Not Reported
	Methotrexate		S	Unknown					Not Reported
	Prednisolone		C	Unknown					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14227910	EXPEDITED (15-DAY)			ZA-SA-2017SA225709			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; Paternal Exposure Timing Unspecified	Chloroquine (Salt Not Specified)			S	Oral			Not Reported
	Arava			S	Oral			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	13670204	EXPEDITED (15-DAY)		OT	CA-SA-2017SA105979		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Arava			S	Oral			Not Reported
	Leflunomide			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Methotrexate Sodium			S	Subcutaneous			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	14230242	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA233499			Female	ZAF

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Depression; Drug Resistance; Dyslipidaemia; Hypertension; Osteoporosis; Rheumatoid Arthritis; Rhinitis Allergic; Spinal Osteoarthritis	Chloroquine (Salt Not Specified)			S	Oral			Not Reported	
	Arava			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown	1 G Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14260150	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2017516200			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>	
Condition Aggravated; Rheumatoid Arthritis	Methotrexate			S		30 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>
11-Dec-2017	13058899	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16- 03		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; Catatonia; Condition Aggravated; Condition Aggravated; Condition Aggravated; Condition Aggravated; Confusional State; Drug Interaction; Dysphonia; Facial Paralysis; Hallucination; Insomnia; Mydriasis; Paranoia; Persecutory Delusion; Suicidal Ideation; Toxic	Risperidone			S	Unknown			Westward	
	Chloroquine			S	Unknown			Hikma	
	Benzotropine Mesylate			S	Unknown			Hikma	
	Diphenhydramine			S	Unknown			Westward	
	Lorazepam			S	Unknown			Westward	
	Lorazepam			S	Unknown			Westward	
	Olanzapine			S	Unknown			Not Reported	
	Olanzapine			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	

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

Encephalopathy; Toxicity	Clonazepam	S	Unknown	Not Reported
To Various Agents	Azithromycin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2017	14268524	EXPEDITED (15-DAY)		HO	ZA-SA-2017SA243005			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>	
Drug Ineffective; Inflammatory Marker Increased; Joint Swelling; Musculoskeletal Stiffness	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Panafcort			S	Oral			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Celebrex			C	Unknown			Not Reported	
	Enbrel			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14268773	EXPEDITED (15-DAY)		DE	DE-SA-2017SA246897		62 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>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Cholestasis; Gamma- Glutamyltransferase Increased; Hepatic Failure	Primaquine Phosphate			S	Unknown	Oral Primaquine (Total Dose 210 Mg)		Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown	Oral Chloquine (Total Dose 5.1 G)		Not Reported	
	Cyclosporin A			C	Unknown			Not Reported	
	Methylprednisolone			C	Unknown			Not Reported	
	Ganciclovir			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2017	14271080	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA241954		42 YR	Male	ZAF

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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>
Carditis; Depression;	Arava			S	Oral			Not Reported
Renal Impairment;	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
Rheumatic Fever;	Methotrexate			S	Unknown			Not Reported
Therapeutic Product Effect Incomplete	Mtcn (Methotrexate)			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	7601161	EXPEDITED (15-DAY)		DS, HO	BR-SANOFI-AVENTIS-2010SA054574		16 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
Aminotransferase Increased; Asthenia;	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
Blood Creatine	Primaquine			S	Unknown			Not Reported
Phosphokinase Increased; Blood Creatinine	Diclofenac Sodium			S	Intramuscular			Not Reported
Increased; Blood Lactate Dehydrogenase								
Increased; Blood Potassium Increased;								
Blood Urea Increased;								
Chills; Chromaturia;								
Myalgia; Myalgia;								
Myoglobinuria; Physical Disability; Renal Tubular Necrosis; Rhabdomyolysis								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2017	14278350	EXPEDITED (15-DAY)		DE, HO	MY-SA-2017SA245495		59 YR	Male	MYS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Dyspnoea;	Primaquine			S	Unknown			Not Reported
Dyspnoea; Epistaxis;	Chloroquine Phosphate			S	Unknown			Not Reported
Haemoptysis; Hypoxia; Lethargy; Lung	Quinine (Salt Not Specified)			S	Intravenous (not			Not Reported

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

Consolidation; Pleural Effusion; Pneumonitis; Pulmonary Haemorrhage; Rales; Respiratory Acidosis; Respiratory Failure; Traumatic Lung Injury	Ceftriaxone	C	otherwise specified)	Not Reported
	Artesunate	C	Intravenous (not otherwise specified)	Not Reported
	Furosemide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2017	14294167	EXPEDITED (15-DAY)		HO	IN-SA-2017SA246776		53 YR	Male	SGP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Gamma-Glutamyltransferase Increased; Hepatic Enzyme Increased	Primaquine			S	Unknown			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2017	14313544	NON-EXPEDITED			US-SA-2017SA140852			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>
Visual Impairment	Aralen			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14314487	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA250373			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>
Neutropenia; Osteoarthritis; Pneumonia; Rheumatoid Arthritis;	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported

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

Transaminases Increased	Methotrexate	S	Unknown	Not Reported
	Azt	S	Unknown	Not Reported
	Corticosteroids	S	Unknown	Not Reported
	Eltroxin	C		Not Reported
	Aspavor	C	Oral	Not Reported
	Enbrel	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14319063	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA258965			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; Diabetes Mellitus Inadequate Control; Hypersensitivity; Impaired Work Ability; Psoriatic Arthropathy; Therapeutic Response Decreased	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Methotrexate			S	Subcutaneous			Not Reported
	Salazopyrin			S	Oral	500mg Bd, 500 Mg, 2x/Day		Not Reported
	Solumedrol			C	Unknown			Not Reported
	Cellcept			C	Unknown			Not Reported
	Prograf			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2017	14330215	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA255493			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>
Cerebrovascular Accident; Impaired Work Ability; Maculopathy; Neutropenia; Rheumatoid Arthritis	Arava			S	Oral			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Forteo			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2017	14331845	EXPEDITED (15-DAY)		DE	US-TORRENT-00004883		25 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Completed Suicide; Toxicity To Various Agents	Zolpidem Tartrate			S	Oral			Unknown
	Chloroquine Phosphate			S	Oral			Unknown
	Alprazolam			S	Oral			Unknown
	Diphenhydramine Hydrochloride			S	Oral			Unknown
	Mirtazapine			S	Oral			Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14333138	EXPEDITED (15-DAY)		HO	FR-SA-2017SA261170		51 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qrs Complex Prolonged; Electrocardiogram Qt Prolonged; Hyperlactacidaemia; Hypokalaemia; Vomiting	Chloroquine Phosphate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14347514	NON-EXPEDITED			US-PFIZER INC- 2017554103		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Benzylpenicillin Potassium			S		20000000 Iu, Unk		Pfizer
	Erythromycin			S		250 Mg, Unk		Not Reported
	Cyclobenzaprine			S		10 Mg, Unk		Not Reported
	Bactrim Ds			S		Unk		Not Reported
	Plaquenil /00072603/			S		200 Mg, Unk		Not Reported
	Chloroquine Phosphate			S		250 Mg, Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	13642284	EXPEDITED (15-DAY)		OT	US-VALIDUS PHARMACEUTICALS LLC-US- 2017VAL000867		40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Leukopenia; Off Label Use	Pentoxifylline			S	Unknown	400 Mg, Tid		Validus
	Mycophenolate Mofetil			S	Unknown	2 G, Qd		Not Reported
	Mycophenolate Mofetil			S	Unknown	Unk, Qd		Not Reported
	Methotrexate			S	Unknown	7.5 Mg, Weekly		Not Reported
	Prednisone			S	Unknown	Unk Unk, Qd		Not Reported
	Hydroxychloroquine /00072603/			S	Unknown	400 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Quinacrine			S	Unknown	100 Mg, Qd		Not Reported
	Dapsone			S	Unknown	100 Mg, Qd		Not Reported
	Acitretin			S	Unknown	20 Mg, Qd		Not Reported
	Tacrolimus			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14418720	NON-EXPEDITED			US-TEVA-791355ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Chloroquine			S	Unknown			Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14441524	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA016645			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>
Headache; Hepatic Fibrosis; Mouth Ulceration;	Arava			S	Oral			Not Reported

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

Nausea; Ocular Toxicity; Rash	Chloroquine (Salt Not Specified)	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Salazopyrin	S	Unknown		Not Reported
	Corticosteroid Nos	S	Unknown		Not Reported
	Humira	S	Unknown	Dose 40mg/2w	Not Reported
	Enbrel	S	Unknown	Dose 50mg/W	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2018	14447130	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018031526		14 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>	
Wrist Deformity	Methotrexate			S	Subcutaneous	25 Mg, Unk		Pfizer	
	Chloroquine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	13378059	EXPEDITED (15-DAY)		OT	CA-SA-2017SA043483		31 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Ineffective; Joint Swelling	Leflunomide			S	Oral	Therapy Duration: 6 Month		Not Reported	
	Chloroquine			S	Unknown	Therapy Duration Reported As: 0.0		Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Amitriptyline			C	Unknown			Not Reported	
	Folate			C	Unknown	Frequency: 1 Every 2 Days		Not Reported	
	Pariet			C	Unknown			Not Reported	
	Vimovo			C	Unknown	500/20 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14474955	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018044567		39 YR	Female	ZAF

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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>	
Spinal Osteoarthritis	Methotrexate Sodium			S	Oral	20 Mg, Weekly		Pfizer	
	Plasmoquine			S		200 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14310442	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA248272		47 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>	
Mastectomy; Spinal Fusion Surgery; Treatment Failure	Arava			S	Oral			Not Reported	
	Chloroquine (Salt Not Specified)			S	Oral			Not Reported	
	Corticosteroid Nos			S	Unknown			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14487510	EXPEDITED (15-DAY)		DS	ZA-SA-2018SA019026		49 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>	
Arthralgia; Fatigue; Gait Disturbance; Hepatitis; Mouth Ulceration; Rash; Unevaluable Event	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2018	14526475	EXPEDITED (15-DAY)		OT	IT-IMPAX LABORATORIES, INC-2018-IPXL-00395			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>	
Myasthenic Syndrome; Myopathy; Product Use In Unapproved Indication	Chloroquine Phosphate			S	Unknown	500 Mg, Daily		Impax	
	Chloroquine Phosphate			S				Impax	
	Prednisone			C	Unknown	75 Mg, Daily		Not Reported	

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Prednisone	C	Unknown	Reduced To 10 Mg, Daily (Maintenance Dose)	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-Feb-2018	14536762	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA029440		31 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>
Bipolar Disorder; Gastroesophageal Reflux Disease; Hypothyroidism	Arava			S	Oral			Not Reported
	Chloroquine Sulfate			S	Unknown			Not Reported
	Azt			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Enbrel			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14546011	NON-EXPEDITED			US-AMGEN- USASP2018020705			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rash	Enbrel			S	Unknown	Unk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Orencia			S	Unknown	Unk		Not Reported
	Xeljanz Xr			C	Oral	11 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	12980233	EXPEDITED (15-DAY)		HO	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-099318		78 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>
Bursitis; Contraindicated Product Administered; Nasal Herpes;	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported

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Nasopharyngitis	Hydroxychloroquine Sulfate	S	Unknown	200 Mg, Qd	Not Reported
	Chloroquine /00001002/	S	Unknown	200 Mg, Qd	Not Reported
	Tocilizumab	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14564251	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA034751		46 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>
Addison'S Disease; Hypertension	Arava			S	Oral			Not Reported
	Chloroquine (Salt Not Specified)			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Polygam			S	Unknown			Not Reported
	Neurontin			S	Unknown			Not Reported
	Tryptanol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2018	14568722	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA038855		27 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>
Cachexia; Infection; Therapeutic Response Decreased	Arava			S	Oral			Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Euthyrox			S	Unknown			Not Reported
	Nexium			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2018	14578341	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA047470			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>
Acute Kidney Injury;	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported

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Deformity; Therapeutic Response Decreased	Arava	S	Unknown	Not Reported
	Methotrexate	S	Oral	Not Reported
	Salazopyrin	S	Oral	Not Reported
	Endoxan	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14584587	EXPEDITED (15-DAY)		OT	US-BAXTER-2018BAX005710			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>
Deformity; Rheumatoid Arthritis	Cyclophosphamide For Injection, Usp			S	Intravenous (not otherwise specified)			Baxter
	Methotrexate			S	Oral			Not Reported
	Salazopyrin			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enap Co			C	Unknown			Not Reported
	Cipalat			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Mar-2018	14588716	EXPEDITED (15-DAY)		HO, LT, OT	ES-IMPAX LABORATORIES, INC-2018-IPXL-00584		45 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Plasmodium Vivax Infection; Splenic Rupture; Thrombocytopenia	Chloroquine Phosphate			S	Unknown	600 Mg, Daily (Day 1)		Impax
	Chloroquine Phosphate			S	Unknown	450 Mg, Daily (Day 2)		Impax
	Chloroquine Phosphate			S	Unknown	450 Mg, Daily (Day 3)		Impax
	Chloroquine Phosphate			S	Unknown	Unk		Impax
	Primaquine			S	Unknown	30 Mg, Daily, For 8 Days		Not Reported
	Primaquine			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2018	14596487	EXPEDITED (15-DAY)		HO	DE-CONCORDIA PHARMACEUTICALS INC.-E2B_00010364		78 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>	
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Concordia	
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Not Reported	
	Methotrexate Sodium			S	Unknown	15 Mg, Qwk		Not Reported	
	Chloroquine /00001002/			S	Unknown	200 Mg, Qd		Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14527180	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018060834			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	Methotrexate			S	Oral	25 Mg, Weekly		Pfizer	
	Salazopyrin			S		Unk		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	
	Endoxan /00021101/			S	Intravenous (not otherwise specified)	500 Mg, Unk		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>
06-Mar-2018	14604797	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA046538			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>	
Arthralgia; Hepatic Fibrosis	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14608615	EXPEDITED (15-DAY)		OT	FR-UCBSA-2018008540		32 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>	
Neutropenia; Pruritus	Keppra			S	Oral	1000 Mg Daily		Ucb	
	Rivotril			S	Oral	1 Mg Daily		Not Reported	
	Nivaquine			S	Oral	Unk		Not Reported	
	Malarone			S	Oral	4 Df Daily		Not Reported	
	Rocephine			S	Intravenous (not otherwise specified)	1 G Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14612313	EXPEDITED (15-DAY)		DE, HO, OT	US-CIPLA LTD.-2018US09957			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypercalcaemia; Therapy Non-Responder	Zoledronic Acid			S	Intravenous (not otherwise specified)	4 Mg, Unk		Cipla	
	Sevelamer			S	Oral	800 Mg, Daily		Invagen	
	Furosemide			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Chloroquine			S	Oral	250 Mg, Daily		Not Reported	
	Prednisolone			S	Unknown	5 Mg, Daily		Not Reported	
	Prednisone /00044702/			S	Oral	30 Mg, 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>
16-Mar-2018	14649684	EXPEDITED (15-DAY)		DS, HO	ZA-SA-2018SA068753			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>	
Arthritis; Disease Progression; Drug Intolerance; Feeding	Arava			S	Oral			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	

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Disorder; Pain; Speech Disorder;	Methotrexate	S	Unknown	Dose: 15-25 Mg	Not Reported
Temporomandibular Joint Syndrome	Salazopyrin	S	Unknown		Not Reported
	Enbrel	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14657259	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018110581		49 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>	
Glucose Tolerance Impaired; Migraine; Pneumonia Viral; Product Use In Unapproved Indication	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer	
	Salazopyrin			S	Oral	500 Mg, 2x/Day		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	
	Arava			C		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>
20-Mar-2018	14432554	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018031319		46 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>	
Addison'S Disease; Hypertension	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer	
	Arava			S		20 Mg, Daily		Not Reported	
	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>
20-Mar-2018	14657508	EXPEDITED (15-DAY)		OT	FR-ROCHE-2090357		32 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>	
Neutropenia; Pruritus	Rivotril			S	Oral			Not Reported	
	Rocephine			S	Intravenous (not otherwise specified)			Not Reported	
	Nivaquine			S	Oral			Not Reported	
	Malarone			S	Oral			Not Reported	

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Keppra			S	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14700846	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA092605		50 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>	
Hypersensitivity; Migraine; Pneumonia Viral	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Cyclosporin			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Aspavor			C	Oral			Not Reported	
	Trazodone			C	Oral			Not Reported	
	Pantocid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2018	14700849	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA091789		49 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>	
Glucose Tolerance Impaired; Migraine; Pneumonia Viral	Chloroquine (Salt Not Specified)			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Arava			C	Unknown			Not Reported	
	Aspavor			C	Oral			Not Reported	
	Trazodone			C	Oral	At Night		Not Reported	
	Pantocid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2018	14702845	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.- 2018ZA14093			Unknown	ZAF

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Arthritis; Iron Deficiency	Meloxicam			S	Unknown	Unk		Cipla	
	Methotrexate			S	Unknown	17.5 Mg, Unk		Not Reported	
	Chloroquine			S	Unknown	1 Df, Weekly		Not Reported	
	Salazopyrin			S	Unknown	1 G, Bid		Not Reported	
	Steroids			S	Unknown	Unk		Not Reported	
	Steroids			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2018	14709577	EXPEDITED (15-DAY)		OT	CA-SA-2018SA090134		33 YR	Female	ZAF
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Intolerance; Investigation Abnormal; Rheumatoid Arthritis	Arava			S	Oral			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			C	Unknown			Not Reported	
	Salazopyrin			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14742120	EXPEDITED (15-DAY)		DS	ZA-SA-2018SA101030		45 YR	Female	ZAF
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Impaired Work Ability; Loss Of Personal Independence In Daily Activities; Therapeutic Response Decreased	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
	Enbrel			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2018	14742160	EXPEDITED (15-DAY)		LT	ZA-SA-2018SA101079			Male	ZAF
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Dyslipidaemia; Glucose Tolerance Impaired; Hypogonadism; Myocardial Infarction; Unevaluable Event	Chloroquine (Salt Not Specified)	S	Oral	Not Reported
	Arava	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Endoxan	S	Unknown	Not Reported
	Mtx	C	Unknown	Not Reported
	Revellex	C	Unknown	Not Reported
	Warfarin	C	Unknown	Not Reported
	Puricos	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2018	14651904	EXPEDITED (15-DAY)		DS, OT	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201803- 000970		32 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>
Blindness; Maculopathy; Retinal Degeneration; Retinal Fovea Disorder; Retinal Fovea Disorder; Retinopathy; Visual Field Defect; Visual Impairment	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine (Salt Not Specified)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	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	Benlysta			S		Unk		Glaxosmithkline
	Benlysta			S		520 Mg, Unk		Glaxosmithkline
	Benlysta			S		560 Mg, Unk		Glaxosmithkline
	Methotrexate			S		Unk		Glaxosmithkline
	Chloroquine Phosphate			S		Unk		Glaxosmithkline

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Administration;
Leukopenia; Overdose;
Polyarthritits

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14776125	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA089971			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>	
Arthralgia; Arthropathy; Drug Intolerance; Impaired Quality Of Life; Joint Swelling; Nausea; Rheumatoid Arthritis; Therapeutic Response Decreased	Arava			S	Oral			Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14779076	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA101528			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>	
Drug Ineffective; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S	Unknown			Not Reported	
	Arava			S	Oral			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Salazopyrin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14779592	EXPEDITED (15-DAY)		HO, OT	IT-IMPAX LABORATORIES, INC- 2018-IPXL-01239		37 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Cardiomegaly; Drug Ineffective; Idiopathic Interstitial Pneumonia; Pleural Effusion	Chloroquine Phosphate			S	Oral	10 Mg/Kg (First And Second Day), Unk		Impax	
	Chloroquine Phosphate			S	Oral	5 Mg/Kg, On Third Day		Impax	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14794102	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2018M1025480		78 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>	
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Methotrexate			S	Unknown	15 Mg, Qwk		Not Reported	
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Mylan	
	Hydroxychloroquine Sulfate			S	Unknown	200 Mg, Qd		Mylan	
	Chloroquine			S	Unknown	200 Mg, Qd		Mylan	
	Tocilizumab			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14064625	EXPEDITED (15-DAY)		HO, OT	RS-IMPAX LABORATORIES, INC-2017-IPXL-02815		29 YR	Female	SRB
<u>Preferred Term</u>	<u>Product</u>	<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; Pneumonitis; Systemic Lupus Erythematosus; Thymus Disorder	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				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>
04-May-2018	13889987	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2017-1517		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Gastrointestinal Disorder; Irritability; Perioral Dermatitis; Product Use Issue; Pruritus; Rash; Rash; Urticaria	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	

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

Chloroquine	S	Unknown	Not Reported
Hydroxychloroquine	S	Unknown	Not Reported
Cortizone	C	Unknown	Not Reported
Hydrocortisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2018	14849091	EXPEDITED (15-DAY)		OT	CA-SA-2018SA116471			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>
Foetal Exposure During Pregnancy; Limb Hypoplasia Congenital	Chloroquine (Salt Not Specified)			S	Transplacental			Not Reported
	Chloroquine (Salt Not Specified)			S	Transplacental			Not Reported
	Chloroquine (Salt Not Specified)			S	Transplacental	At 27 Weeks		Not Reported
	Chloroquine (Salt Not Specified)			S	Transplacental	At 27 Weeks		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14851387	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201805-001478		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ascites; Atrioventricular Block Complete; Cardiac Failure Congestive; Cardiomyopathy; Ejection Fraction Decreased; Muscular Weakness; Oedema Peripheral	Hydroxychloroquine			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>
08-May-2018	14861280	EXPEDITED (15-DAY)		OT	US-SA-2018SA118066		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ascites; Atrioventricular Block Complete; Cardiac	Hydroxychloroquine Sulfate			S	Unknown			Not Reported

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

Failure Congestive; Cardiomyopathy; Ejection Fraction Decreased; Muscular Weakness; Oedema Peripheral	Chloroquine (Salt Not Specified)	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>
10-May-2018	13876370	EXPEDITED (15-DAY)		OT	CA-AMGEN- CANSL2017074701		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Dermatitis; Dizziness; Gastrointestinal Disorder; Headache; Irritability; Nausea; Rash; Urticaria	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen	
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen	
	Methotrexate			S	Unknown	10 Mg, Qd		Not Reported	
	Methotrexate			S	Subcutaneous	25 Mg, Qwk		Not Reported	
	Chloroquine			S	Unknown	400 Mg, Qwk		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Qwk		Not Reported	
	Cortizone			C				Not Reported	
	Hydrocortisone			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>
10-May-2018	14874712	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018062485		61 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>	
Drug Ineffective; Rheumatoid Arthritis; Skin Ulcer	Salazopyrin			S		2 G, Daily		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	
	Methotrexate			C	Subcutaneous	25 Mg, Weekly		Not Reported	
	Arava			C		20 Mg, Daily		Not Reported	
	Prednisone			C		10 Mg, Daily		Not Reported	
	Enbrel			C	Subcutaneous	50 Mg, Weekly (50mg Sc Weekly X 6)		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>
10-May-2018	14875660	EXPEDITED (15-DAY)		HO	ZA-SA-2018SA125032		18 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>	
Bipolar Disorder; Drug Ineffective	Arava			S	Oral			Not Reported	
	Plasmoquine			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14543577	EXPEDITED (15-DAY)		OT	DE-IMPAX LABORATORIES, INC-2018-IPXL-00429		52 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myasthenic Syndrome	Chloroquine Phosphate			S	Unknown	250 Mg, Bid		Impax	
	Prednisolone			C	Unknown	10 To 20 Mg/Day		Not Reported	
	Prednisolone			C	Unknown	2.5 Mg, Unk		Not Reported	
	Voltaren			C	Unknown	50 Mg, Tid		Not Reported	
	Euglucon			C	Unknown	5 Mg, Unk		Not Reported	
	Tagamet			C	Unknown	200 Mg, 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>
11-May-2018	14838569	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017225076		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Dizziness; Gastrointestinal Disorder; Headache; Irritability; Nausea; Perioral Dermatitis; Rash; Rash; Urticaria	Enbrel			S	Subcutaneous	50 Mg, Weekly		Pfizer	
	Methotrexate Sodium			S	Unknown	10 Mg, Qd		Pfizer	
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Pfizer	
	Chloroquine			S	Unknown	400 Mg, Weekly		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Qwk		Not Reported	
	Cortizone			C		Unk		Not Reported	

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Hydrocortisone			C			Unk			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-May-2018	14204504	EXPEDITED (15-DAY)		OT		ZA-PFIZER INC-2017497849			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>		
Condition Aggravated;	Methotrexate				S		25 Mg, Weekly		Pfizer		
Dyslipidaemia;	Chloroquine				S		200 Mg, Daily		Not Reported		
Maculopathy; Neuropathy	Arava				S		20 Mg, Daily		Not Reported		
Peripheral											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2018	14779487	EXPEDITED (15-DAY)		HO, OT		ES-IMPAX LABORATORIES, INC-2018-IPXL-01243		43 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Respiratory Distress Syndrome; Anaemia;	Chloroquine Phosphate				S	Oral	Unk		Impax		
Atelectasis; Generalised	Primaquine				S	Oral	Unk		Not Reported		
Oedema; Hypertensive	Irbesartan				C	Unknown	Unk		Not Reported		
Cardiomyopathy;	Insulin				C	Unknown	Unk		Not Reported		
Hypotension; Pleural Effusion; Pneumonia;											
Pneumonia Acinetobacter;											
Pulmonary Oedema;											
Pyrexia; Renal Impairment											
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-May-2018	14779488	EXPEDITED (15-DAY)		DE, HO, OT		MY-IMPAX LABORATORIES, INC-2018-IPXL-01241		59 YR	Male	MYS	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Kidney Injury; Acute Respiratory Distress Syndrome; Atrial Fibrillation; Enterobacter Sepsis; Epilepsy;	Chloroquine Phosphate				S	Unknown	150 Mg, Unk		Impax		
	Primaquine				S	Unknown	30 Mg, Unk		Not Reported		
	Quinine				S	Intravenous (not	850 Mg Dose (On Day 4),		Not Reported		

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Epistaxis; Hypotension;
Metabolic Acidosis;
Pleural Effusion;
Pneumonia; Pulmonary
Haemorrhage; Respiratory
Acidosis; Respiratory
Failure

otherwise specified) Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14901190	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018196305		36 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>	
Systemic Lupus Erythematosus	Methotrexate Sodium			S		2.5 Mg, Unk		Pfizer	
	Bilacor			S		5 Mg, Unk		Not Reported	
	Topalex			S		100 Mg, Unk		Not Reported	
	Adco-Simvastatin			S		10 Mg, Unk		Not Reported	
	Epitec			S		50 Mg, Unk		Not Reported	
	Epitec			S		100 Mg, Unk		Not Reported	
	Nivaquine /00001001/			S		200 Mg, Unk		Not Reported	
	Spiractin /00006201/			S		25 Mg, Unk		Not Reported	
	Yelate			S		60 Mg, Unk		Not Reported	
	Fluanxol /00109702/			S		1 Mg, Unk		Not Reported	
	Altosec /00661201/			S		20 Mg, Unk		Not Reported	
	Adco Zopimed			S		7.5 Mg, Unk		Not Reported	
	Tranqipam			S		2.5 Mg, Unk		Not Reported	
	Maxalt			S		10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14204497	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2017498665		36 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>	
Carditis; Depression; Drug	Methotrexate			S		25 Mg, Weekly		Pfizer	

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Ineffective; Dyslipidaemia; Renal Impairment; Rheumatic Fever	Azithromycin	S	75 Mg, Daily	Pfizer
	Chloroquine	S	200 Mg, 1x/Day	Not Reported
	Arava	S	20 Mg, 1x/Day	Not Reported
	Minocycline	S	60 Mg, 1x/Day	Not Reported
	Enbrel	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951752	EXPEDITED (15-DAY)		HO, OT	ZA-009507513- 1805ZAF013951		36 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>
Adverse Event; Systemic Lupus Erythematosus	Maxalt 10			S	Oral			Merck
	Methotrexate Sodium			S		2.5 Mg, Unk		Not Reported
	Bilocor			S		5 Mg, Unk		Not Reported
	Topalex			S		100 Mg, Unk		Not Reported
	Adco Simvastatin			S		10 Mg, Unk		Not Reported
	Epitec			S		50 Mg, Unk		Not Reported
	Epitec			S		100 Mg, Unk		Not Reported
	Nivaquine			S		200 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Yelate			S				Not Reported
	Fluanxol			S				Not Reported
	Altosec			S				Not Reported
	Adco Zopimed			S				Not Reported
	Tranqipam			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-Jun-2018	14982600	EXPEDITED (15-DAY)		OT	CA-IPCA LABORATORIES LIMITED-IPC-2018-CA- 001222		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vitiligo	Chloroquine			S	Oral	125 Mg, Unk		Ipca

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Chloroquine			S	Oral	250 Mg, Qd			Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14982601	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.- 2018ZA18961			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>	
Systemic Lupus Erythematosus	Lamotrigine			S	Unknown	50 Mg, Unk		Cipla	
	Lamotrigine			S	Unknown	100 Mg, Unk		Cipla	
	Topalex			S	Unknown	100 Mg, Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	2.5 Mg, Unk		Not Reported	
	Bilocor			S	Unknown	5 Mg, Unk		Not Reported	
	Adco-Simvastatin			S	Unknown	10 Mg, Unk		Not Reported	
	Nivaquine /00001001/			S	Unknown	200 Mg, Unk		Not Reported	
	Spiractin /00006201/			S	Unknown	25 Mg, Unk		Not Reported	
	Yelate			S	Unknown	60 Mg, Unk		Not Reported	
	Fluanxol /00109702/			S	Unknown	1 Mg, Unk		Not Reported	
	Altosec /00661201/			S	Unknown	20 Mg, Unk		Not Reported	
	Adco Zopimed			S	Unknown	7.5 Mg, Unk		Not Reported	
	Tranqipam			S	Unknown	2.5 Mg, Unk		Not Reported	
	Maxalt			S	Unknown	10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14988504	EXPEDITED (15-DAY)		HO, OT	ZA-DRREDDYS- SAF/SAF/18/0099928		36 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>	
Hospitalisation; Systemic Lupus Erythematosus	Yelate			S				Not Reported	
	Methotrexate Sodium			S				Not Reported	
	Bilocor			S				Not Reported	
	Topalex			S				Not Reported	
	Adco-Simvastatin			S				Not Reported	
	Epitec			S				Not Reported	
	Nivaquine			S				Not Reported	

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	Spiractin (Spironolactone)	S		Not Reported
	Fluanxol	S		Not Reported
	Altosec	S		Not Reported
	Adco-Zopimed	S		Not Reported
	Tranqipam	S		Not Reported
	Maxalt	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-2018	15003270	EXPEDITED (15-DAY)		OT	PHHY2018ZA018395		36 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>
C-Reactive Protein Increased; Carditis; Depression; Dyslipidaemia; Renal Impairment; Rheumatic Fever	Minocycline			S	Unknown	60 Mg, Qd		Novartis
	Azithromycin			S	Unknown	75 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qw		Not Reported
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15106163	EXPEDITED (15-DAY)		DE, HO, OT	HU-IPCA LABORATORIES LIMITED-IPC-2018-HU-001433			Unknown	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>
Cardiomyopathy	Chloroquine			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>
06-Jul-2018	15114611	EXPEDITED (15-DAY)		HO, OT	HU-IMPAX LABORATORIES, INC- 2018-IPXL-02292		67 YR	Unknown	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>
Cardiac Failure; Product Use In Unapproved Indication; Restrictive Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax
	Chloroquine Phosphate			S				Impax

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2018	15114881	EXPEDITED (15-DAY)		DE, HO	HU-IMPAX LABORATORIES, INC- 2018-IPXL-02291		71 YR	Unknown	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>	
Cardiac Failure; Product Use In Unapproved Indication; Restrictive Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				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>
06-Jul-2018	15115463	EXPEDITED (15-DAY)		HO, OT	HU-IMPAX LABORATORIES, INC- 2018-IPXL-02290		64 YR	Unknown	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>	
Cardiac Failure; Product Use In Unapproved Indication; Restrictive Cardiomyopathy	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Chloroquine Phosphate			S				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>
20-Jul-2018	14573924	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018073617		17 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; Fibula Fracture; Gastritis	Methotrexate Sodium			S		20 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>
24-Jul-2018	14271602	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA241940		77 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>	
Bronchiolitis; Deformity; Dyslipidaemia;	Chloroquine (Salt Not Specified)			S	Oral	200 Mg,Qd		Sanofi	

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Maculopathy	Arava	S	Oral	20 Mg,Qd	Sanofi
	Azt	S	Unknown	Unk Unk,Unk	Not Reported
	Gold	S	Unknown	Unk Unk,Unk	Not Reported
	Methotrexate	S	Unknown	25 Mg,Qw	Not Reported
	Salazopyrin	S	Unknown	1 G,Bid	Not Reported
	Enbrel	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>
30-Jul-2018	15215495	EXPEDITED (15-DAY)		HO, OT	NL-IMPAX LABORATORIES, INC- 2018-IPXL-02500		27 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>	
Cardiac Arrest; Hypokalaemia; Intentional Overdose; Suicide Attempt	Chloroquine Phosphate			S	Unknown	Unk		Impax	
	Clonidine			C	Unknown	Unk		Not Reported	
	Dextroamphetamine			C	Unknown	Unk		Not Reported	
	Promethazine			C	Unknown	Unk		Not Reported	
	Flurazepam			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-2018	14720817	EXPEDITED (15-DAY)		HO, OT	PL-MYLANLABS- 2018M1021424		44 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>	
Central Nervous System Lymphoma; Necrotising Herpetic Retinopathy; Product Use In Unapproved Indication; Varicella Zoster Virus Infection; Visual Impairment	Azathioprine			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	2 G Per Day		Not Reported	
	Prednisone			S	Unknown	20 Mg, Per Day		Not Reported	
	Prednisone			S	Oral	40 Mg, Qd		Not Reported	
	Cyclophosphamide			S	Intravenous (not otherwise specified)	750 Mg Per Day		Mylan	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Mylan	
	Arechin			S	Unknown	Unk		Mylan	

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Arechin			C			Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15228329	EXPEDITED (15-DAY)		OT	ZA-BAYER-2018-139596		42 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>	
Arthralgia; Arthralgia;	Aleve			S	Unknown	Unk		Bayer	
Bursitis; Dry Mouth;	Salazopyrin			S	Unknown	1 G, Bid		Not Reported	
Fatigue; Inflammatory	Methotrexate Sodium			S		20 Mg, Ow		Not Reported	
Pain; Joint Effusion; Joint	Plasmoquine			S	Unknown	200 Mg, Unk		Not Reported	
Swelling; Joint Swelling;	Prednisone			S	Unknown	5 Mg, Qd		Not Reported	
Joint Swelling; Joint									
Swelling; Joint Swelling;									
Joint Swelling; Joint									
Swelling; Metatarsalgia;									
Musculoskeletal Pain;									
Musculoskeletal Stiffness;									
Pain; Pain In Extremity;									
Palmar Erythema;									
Sjogren'S Syndrome									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2018	15132629	EXPEDITED (15-DAY)		OT	BR-AMGEN-BRASP2018078247		69 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>	
Aphonia; Back Pain;	Enbrel			S	Unknown	1 Application Of 50 Mg Per Week		Amgen	
Bronchitis; Condition	Chloroquine			S	Oral	1 Tablet, Daily		Not Reported	
Aggravated; Cough;	Verapamil			C	Unknown	Unk		Not Reported	
Dizziness; Dyspnoea;	Losartan			C	Unknown	Unk		Not Reported	
Eating Disorder; Fatigue;	Simvastatin			C	Unknown	Unk		Not Reported	
Gait Disturbance; Immune									
System Disorder; Pleural									
Effusion; Pneumonia;									
Secretion Discharge;									
Visual Impairment									

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2018	15251092	EXPEDITED (15-DAY)		HO, LT, OT	NL-NATCO PHARMA-2018NAT00135		27 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>	
Cardiac Arrest; Hypokalaemia; Intentional Overdose; Suicide Attempt; Toxicity To Various Agents	Chloroquine Phosphate			S	Oral			Natco Pharma	
	Clonidine			C				Not Reported	
	Dextroamphetamine			C				Not Reported	
	Flurazepam			C				Not Reported	
	Promethazine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2018	15272122	EXPEDITED (15-DAY)		OT	CA-SA-2018SA145865		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vitiligo	Chloroquine (Salt Not Specified)			S	Oral	125 Mg, Biw		Sanofi	
	Chloroquine (Salt Not Specified)			S	Oral	250 Mg, Qd		Sanofi	
	Tamoxifen			C				Not Reported	
	Levothyroxine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15274733	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-940003		78 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>	
Bursitis; Contraindicated Product Administered; Nasal Herpes; Nasopharyngitis	Methotrexate Sodium			S	Unknown			Barr	
	Abatacept			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	200 Milligram Daily;		Not Reported	
	Chloroquine /00001002/			S	Unknown	200 Milligram Daily;		Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15312696	EXPEDITED (15-DAY)		DE, HO, OT	FR-SA-2018SA221399			Female	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Coma; Toxicity To Various Agents	Chloroquine (Salt Not Specified)			S		Indeterminate Dose Of Chloroquine But Probably Below 2 G		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2018	15312698	EXPEDITED (15-DAY)		OT	FR-SA-2018SA221163		23 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>	
Depressed Level Of Consciousness; Nausea; Overdose; Sinus Tachycardia; Vomiting	Chloroquine (Salt Not Specified)			S		1 G		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15050168	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP015755		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Leflunomide			S	Unknown	20 Mg, Qd		Apotex	
	Arava			S	Oral	20 Mg, Qd		Not Reported	
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported	
	Enbrel			S	Unknown	20 Mg, Qd		Not Reported	
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Q.Wk.		Not Reported	
	Plaquenil /00072602/			S	Unknown	250 Mg, Qd		Not Reported	
	Sulfasalazine			S	Unknown	1 G, Bid		Not Reported	
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15365998	EXPEDITED (15-DAY)		OT	PHHY2018ZA092555			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>	

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End Stage Renal Disease	Ciclosporin	S	Unknown	100 Mg, Bid	Novartis
	Chloroquine	S	Unknown	200 Mg, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378201	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018365115			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
C-Reactive Protein Increased; Drug Hypersensitivity; Haematocrit Decreased; Red Blood Cell Count Decreased; Tuberculosis; White Blood Cell Count Decreased	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer
	Salazopyrin			S				Pfizer
	Chloroquine			S		20 Mg, Unk		Not Reported
	Prednisone			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15378657	EXPEDITED (15-DAY)		HO	IN-SA-2018SA250621		12 YR	Male	IND

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Methaemoglobin; Cyanosis; Skin Discolouration	Primaquine			S		Unk		Sanofi
	Chloroquine (Salt Not Specified)			S		Unk		Sanofi

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2018	15379532	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA249033			Female	ZAF

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Renal Failure	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi
	Prednisone			S		30 Mg		Not Reported
	Methotrexate			C		20 Mg, Qw		Not Reported
	Cyclosporine			S		100 Mg, Bid		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15379550	EXPEDITED (15-DAY)		DE, HO, OT	US-SA-2018SA248198		8 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Circulatory Collapse; Cough; Drug Ineffective; Fatigue; Malaise; Plasmodium Falciparum Infection; Pyrexia; Vomiting	Chloroquine (Salt Not Specified)			S		Initial Dose		Sanofi	
	Chloroquine (Salt Not Specified)			S		Weekly Regimen		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2018	15138777	EXPEDITED (15-DAY)		OT	BR-AMGEN-BRASP2018094514		48 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 Pain Upper; Fear; Feeling Abnormal; Feeling Of Despair; Fibromyalgia; Hepatic Cirrhosis; Memory Impairment; Nausea; Retching; Taste Disorder	Enbrel			S	Unknown	50 Mg, Weekly		Amgen	
	Enbrel			S	Unknown	100 Mg, Monthly (50 Mg, Twice Monthly)		Amgen	
	Methotrexate Sodium			S	Unknown	Unk		Not Reported	
	Chloroquine			S	Unknown	Unk		Not Reported	
	Alprazolam			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-Sep-2018	15391780	EXPEDITED (15-DAY)		HO, OT	IN-SA-2018SA256335			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>	
Anaemia; Haemoglobinuria; Intravascular Haemolysis; Pallor; Renal Failure	Chloroquine (Salt Not Specified)			S		5 Mg/Kg Body Weight		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15391781	EXPEDITED (15-DAY)		HO, OT	IN-SA-2018SA256310			Male	IND

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Haemoglobinuria; Intravascular Haemolysis; Pallor; Renal Failure	Chloroquine (Salt Not Specified)			S		15 Mg/Kg Body Weight.		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>
19-Sep-2018	15404211	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA255646		55 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>	
Unevaluable Event; Vasculitis	Arava			S	Unknown	Unk Unk, Unk		Sanofi	
	Methotrexate			S	Unknown	Unk Unk, Unk		Not Reported	
	Chloroquine (Salt Not Specified)			S	Unknown	Unk Unk, Unk		Sanofi	
	Salazopyrin			S	Unknown	Unk Unk, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15434782	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2018387510		62 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>	
Condition Aggravated; Pulmonary Embolism; Rheumatoid Arthritis	Methotrexate			S		25 Mg, Daily		Pfizer	
	Salazopyrin			S		1.5 G, 2x/Day		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	
	Solumedrol			C	Intravenous (not otherwise specified)	250 Mg, Ivi Stat		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2018	15443528	EXPEDITED (15-DAY)		HO, OT	GB-SA-2018SA176522		48 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelinating Polyneuropathy; Drug Interaction; Muscular	Chloroquine (Salt Not Specified)			S		Unk		Sanofi	
	Chloroquine (Salt Not Specified)			S		Unk		Sanofi	

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Weakness; Myopathy; Off Label Use; Paraesthesia; Toxicity To Various Agents	Mepacrine Hydrochloride	S	Unk	Sanofi
	Mepacrine Hydrochloride	S	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>
28-Sep-2018	15446355	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2017543722		75 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>
Herpes Zoster; Ophthalmic Herpes Zoster	Enbrel			S		50 Mg, Every 7 Days		Pfizer
	Methotrexat Lederle			S		20 Mg, Weekly		Pfizer
	Azulfidine Ra			S		2000 Mg, Daily		Pfizer
	Hydroxychloroquine/Chloroquine			S		400 Mg, Daily		Not Reported
	Prednisolone			C	Oral	5 Mg, Daily		Not Reported
	Pregabalin			C				Not Reported
	Amitriptylin			C				Not Reported
	Rubiefol			C		Unk		Not Reported
	Quensyl			C		Unk		Not Reported
	Coaprovel			C		Unk		Not Reported
	L-Thyroxine [Levothyroxine Sodium]			C		Unk		Not Reported
	Pantoprazole			C		Unk		Not Reported
	Dorzocomp Vision			C		Unk		Not Reported
	Atorvastatin Calcium			C		Unk		Not Reported
	Celecoxib			C		Unk		Not Reported
	Dekristol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15452597	EXPEDITED (15-DAY)		OT	GB-IMPAX LABORATORIES, INC-2018-IPXL-03135		19 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>
Blindness; Generalised Tonic-Clonic Seizure;	Chloroquine Phosphate			S	Unknown	Unk		Impax

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Urticaria

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15455572	EXPEDITED (15-DAY)		HO	NG-IMPAX LABORATORIES, INC- 2018-IPXL-03199		16 YR	Female	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysarthria; Dyskinesia; Torticollis; Urinary Tract Infection	Chloroquine Phosphate Paracetamol			S S	Unknown Unknown	2 Tablets, Unk 2 Tablets, Unk		Impax Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Oct-2018	15455614	EXPEDITED (15-DAY)		HO	BE-IMPAX LABORATORIES, INC- 2018-IPXL-03203		62 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transient Global Amnesia	Chloroquine Phosphate Chloroquine Phosphate			S S	Unknown Oral	Unk 300 Mg, Morning		Impax 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>
04-Oct-2018	15465703	EXPEDITED (15-DAY)		HO	NG-IMPAX LABORATORIES, INC- 2018-IPXL-03313		12 YR	Male	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Dysphagia; Muscle Contractions Involuntary; Salivary Hypersecretion	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>
04-Oct-2018	15465704	EXPEDITED (15-DAY)		HO	NG-IMPAX LABORATORIES, INC- 2018-IPXL-03198		12 YR	Male	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Dysphagia; Muscle Contractions	Chloroquine Phosphate			S	Oral	Two Tablets		Impax	

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Involuntary; Salivary Hypersecretion	Chloroquine Phosphate	S	Oral	Unk	Impax				
	Chloroquin Phosphate	C		Unk	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15466142	EXPEDITED (15-DAY)		HO, OT	CH-IMPAX LABORATORIES, INC-2018-IPXL-03224		68 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Status Epilepticus	Chloroquine Phosphate			S	Unknown	100 Mg, Daily		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>
05-Oct-2018	15470324	EXPEDITED (15-DAY)		HO	NG-IMPAX LABORATORIES, INC-2018-IPXL-03200		26 YR	Male	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyskinesia; Muscle Contractions Involuntary; Paraesthesia; Torticollis	Chloroquine Phosphate			S	Unknown	2 Tablets, Unk		Impax	
	Aspirin			S	Unknown	2 Tablets, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Oct-2018	15387287	EXPEDITED (15-DAY)		HO, OT	PL-SAKK-2018SA253951AA		26 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>	
Agranulocytosis; Asthenia; Bone Marrow Failure; Cyanosis; Dizziness; Dyspnoea; Methaemoglobinaemia; Mucosal Erosion; Pyrexia; Skin Discolouration; Tonsillar Erythema	Primaquine			S		15 Mg, Qd; On Day 7		Sanofi	
	Chloroquine (Salt Not Specified)			S	Intramuscular	1 Ampoule		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	14609902	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018090254		51 YR	Female	ZAF

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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>	
Hepatic Steatosis; Macular Degeneration	Methotrexate Sodium			S		15 Mg, Weekly		Pfizer	
	Nivaquine			S		Unk		Not Reported	
	Salazopyrin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15451954	EXPEDITED (15-DAY)		HO, OT	OM-IMPAX LABORATORIES, INC-2018-IPXL-03155		36 YR	Male	OMN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Agitation; Asthenia; Confusional State; Dyspnoea; Headache; Hypokalaemia; Hypotension; Intentional Overdose; Metabolic Acidosis; Nausea; Respiratory Arrest; Seizure; Somnolence; Suicide Attempt; Vomiting	Chloroquine Phosphate			S	Unknown	3.75 G (25x150 Mg Base Tablet)		Impax	
	Proguanil			S	Unknown	2 G (20 Tablets Of 100 Mg)		Not Reported	
	Paracetamol			S	Unknown	1.5 G (6 Tablets Of 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>
11-Oct-2018	15489028	EXPEDITED (15-DAY)		OT	OM-IMPAX LABORATORIES, INC-2018-IPXL-03340		25 YR	Female	OMN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Maternal Exposure During Pregnancy	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>
12-Oct-2018	15494052	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA279489			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>	
Pulmonary Embolism;	Methotrexate			S		Unk		Not Reported	

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Rheumatoid Arthritis	Chloroquine (Salt Not Specified)	S	Unk	Sanofi
	Salazopyrin	S	1.5 G, Tid	Not Reported
	Solumedrol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Oct-2018	15494689	EXPEDITED (15-DAY)		HO	FR-IMPAX LABORATORIES, INC- 2018-IPXL-03322		59 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Status Epilepticus	Chloroquine Phosphate			S	Unknown	100 Mg, Daily, 1 Tablet		Impax
	Carbamazepine			C	Unknown	400 Mg, Daily		Not Reported
	Proguanil Hydrochloride			C	Unknown	200 Mg, Daily, 1 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>
15-Oct-2018	15451484	EXPEDITED (15-DAY)		HO, OT	OM-IMPAX LABORATORIES, INC- 2018-IPXL-03154		25 YR	Female	OMN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Induced; Alanine Amino transferase Increased; Aspartate Amino transferase Increased; Cardiac Arrest; Hypokalaemia; Hypotension; Intentional Overdose; Maternal Exposure During Pregnancy; Metabolic Acidosis; Pyrexia; Seizure; Sinus Tachycardia; Ventricular Extrasystoles; Ventricular Fibrillation	Chloroquine Phosphate			S	Unknown	2.7 G, Unk		Impax
	Twinject/Adrenacllick			S	Intravenous (not otherwise specified)	1 Mg, Repeated At 1 Minute Intervals		Impax
	Twinject/Adrenacllick			S	Intravenous (not otherwise specified)	5 Mg, 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-Oct-2018	15500850	EXPEDITED (15-DAY)		HO	ID-IMPAX LABORATORIES, INC- 2018-IPXL-03342		37 YR	Female	IDN

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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>	
Dyspnoea;	Chloroquine Phosphate			S	Unknown	Unk		Impax	
Hypocalcaemia;	Chloroquine Phosphate			S				Impax	
Hypokalaemia;									
Hypomagnesaemia;									
Hyponatraemia; Metabolic									
Alkalosis; 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>
18-Oct-2018	14210601	EXPEDITED (15-DAY)		DS	ZA-PFIZER INC-2017496011		33 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	Methotrexate			S		25 Mg, Weekly		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	
	Azt			S		100 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	12415178	EXPEDITED (15-DAY)		HO, OT	PL-ACCORD-040855		44 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>	
Central Nervous System	Mycophenolic Acid			S				Accord	
Lymphoma; Necrotising	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	
Herpetic Retinopathy	Arechin			S				Not Reported	
	Prednisone			S		Previously Received Oral Prednisone (40 Mg/Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15538917	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018424979			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>	
Alanine Aminotransferase	Salazopyrin			S		1 G, Daily		Pfizer	

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Increased; Aspartate Aminotransferase	Chloroquine	S			200 Mg, Daily	Not Reported
Increased; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Methotrexate	C	Oral		25 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>
23-Oct-2018	14038461	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017422851		48 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>	
Cachexia; Carpal Tunnel Syndrome; Drug Ineffective; Dyslipidaemia	Methotrexate			S		30 Ug, Weekly		Pfizer	
	Solu-Medrol			S	Intravenous (not otherwise specified)	500 Ug, Monthly		Pfizer	
	Methylprednisolone			S	Oral	Unk (5)		Pfizer	
	Chloroquine			S		200 Ug, Daily		Not Reported	
	Arava			S		20 Ug, Daily		Not Reported	
	Endoxan /00021101/			S	Intravenous (not otherwise specified)	500 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15538059	EXPEDITED (15-DAY)			PL-PFIZER INC-2018423092		49 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>	
Abdominal Pain Upper	Methylprednisolone			S		32 Mg, 1x/Day		Pfizer	
	Chloroquine (Salt Not Specified)			S		250 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559736	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.-2018ZA22149			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>	
C-Reactive Protein Increased; Lymphocyte Count Decreased; Red	Coxflam			S	Unknown	15 Mg, Daily		Cipla	
	Simvastatin			S	Unknown	20 Mg, Daily		Not Reported	

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

Blood Cell Sedimentation Rate Increased;	Salazopyrin	S	Unknown	1 G, Bid	Not Reported
Rheumatoid Factor Increased;	Methotrexate Sodium	S	Unknown	20 Mg, Weekly	Not Reported
Spondylolisthesis	Nivaquine /00001001/	S	Unknown	200 Mg, Daily	Not Reported
	Folic Acid	S	Unknown	5 Mg, Daily	Not Reported
	Prednisone	S	Unknown	10 Mg, Per Day, 4 Times A 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>
29-Oct-2018	15562375	EXPEDITED (15-DAY)		HO, OT	FR-SA-2018SA295536		24 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>
Encephalopathy	Nivaquine			S	Oral	500 Mg, Qd		Sanofi

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15577924	NON-EXPEDITED			US-PFIZER INC-2018452511		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Erythromycin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Cephalexin Hcl			S		Unk		Not Reported
	Chloroquine			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>
05-Nov-2018	15587732	EXPEDITED (15-DAY)		OT	ZA-SAKK-2018SA301051AA			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>
Alanine Aminotransferase Increased; Arthropathy; Aspartate	Arava			S		Unk		Sanofi
	Chloroquine (Salt Not Specified)			S		Unk		Sanofi

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Aminotransferase Increased; Drug Intolerance; Psoriatic Arthropathy; Synovitis	Methotrexate	C	Unk	Not Reported
	Salazopyrin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15451451	EXPEDITED (15-DAY)		HO, OT	DE-IMPAX LABORATORIES, INC-2018-IPXL-03158		50 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>
Anaemia Macrocytic; Bundle Branch Block Right; Coma; Depression; Generalised Tonic-Clonic Seizure; Hypoglycaemia; Intentional Overdose; Pneumonia Aspiration; Suicide Attempt	Chloroquine Phosphate			S	Oral	3.75 G, (15 Tablets), Single		Impax
	Chloroquine Phosphate Alcohol			S				Impax
				S	Oral	Unk, Some		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2018	15591958	EXPEDITED (15-DAY)		OT	CA-MIDATECHPHARMA-2018-CA-000965		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ichthyosis; Porphyria Non-Acute; Scleroderma; Vitiligo	Tamoxifen (Non-Specific)			S				Midatech Pharma
	Chloroquine			S	Oral	250 Mg Daily		Not Reported
	Levothyroxine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15598228	EXPEDITED (15-DAY)		HO, OT	CH-SAKK-2018SA299930AA		39 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Tonic-Clonic Seizure; Myoclonus	Plaquenil			S				Sanofi
	Chloroquine (Salt Not Specified)			S				Sanofi
	Depakine [Valproate Sodium]			C				Not Reported
	Depakine [Valproate Sodium]			C		Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15182738	EXPEDITED (15-DAY)		DS, OT	BR-SA-2018SA190963			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>
Back Pain; Bronchitis; Condition Aggravated; Cough; Dizziness; Dysphonia; Dyspnoea; Eating Disorder; Fatigue; Gait Disturbance; Hernia; Immunodeficiency; Pleural Effusion; Pneumonia; Unevaluable Event; Unevaluable Event; Visual Impairment	Losartan Potassium Simvastatin Chloroquine Enbrel Verapamil			S S S S S	Oral	Unk Unk 1 Tablet Daily 1 Application Of 50 Mg Weekly Unk		Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15348256	EXPEDITED (15-DAY)		DS, HO, OT	AU- GLAXOSMITHKLINE- AU2017GSK075527		30 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Agitation; Amnesia; Anger; Anxiety; Brain Injury; Cardiac Arrest; Coma; Condition Aggravated; Cyp2d6 Polymorphism; Depression; Disturbance In Attention; Dizziness; Drug Ineffective; Extra Dose Administered; Fracture; Ill-Defined Disorder; Memory Impairment; Mood Swings; Neurotoxicity; Paranoia; Performance Status Decreased; Poor Quality Sleep; Post-Traumatic	Tafenoquine Mefloquine Chloroquine Primaquine			S S S S		200 Mg, We Unk Unk Unk		Glaxosmithkline Not Reported Not Reported Not Reported

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Stress Disorder;
Psychiatric Symptom;
Speech Disorder; Stress;
Suicidal Ideation; Suicide
Attempt

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2018	15608589	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA305053		20 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>	
Blood Chloride Increased;	Arava			S		Unk		Sanofi	
Blood Creatine Decreased; Iron Deficiency; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S		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>
12-Nov-2018	15608876	EXPEDITED (15-DAY)		HO, OT	CA-SA-2018SA310689		45 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Bifascicular Block; Bradycardia; Cardiac Failure; Cardiomyopathy; Dilatation Atrial; Dyspnoea; Fatigue; Kidney Congestion; Mitral Valve Incompetence; Oedema Peripheral; Orthopnoea; Tricuspid Valve Incompetence; Ventricular Hypertrophy; Weight Increased	Chloroquine (Salt Not Specified)			S	Oral	250 Mg, Qd		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15609971	EXPEDITED (15-DAY)		HO	CA-ORION CORPORATION ORION PHARMA-TREX2018-		61 YR	Male	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Knee Arthroplasty; Malaise; Pain; Post Procedural Complication; Product Complaint; Sensory Loss; Swelling; Therapeutic Product Effect Incomplete; Thrombosis; Unevaluable Event	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported
	Sulfasalazine			S	Oral			Not Reported
	Arava			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Plaquenil			S	Oral			Not Reported
	Remicade			S	Unknown			Not Reported
	Xeljanz			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15613818	EXPEDITED (15-DAY)		DE	ZA-PFIZER INC- 2018464538		81 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>
Cardiac Failure; Renal Failure	Methotrexate			S		2.5 Mg, Unk		Pfizer
	Premarin			S		0.625 Mg, Unk		Pfizer
	Puricos			S		300 Mg, Unk		Not Reported
	Nivaquine [Chloroquine]			S		200 Mg, Unk		Not Reported
	Spiractin (Spironolactone)			S		25 Mg, Unk		Not Reported
	Carloc			S		6.25 Mg, Unk		Not Reported
	Be-Tabs Folic Acid			S		5 Mg, Unk		Not Reported
	Puresis			S		40 Mg, Unk		Not Reported
	Slow Mag [Magnesium Chloride]			S		535 Mg, Unk		Not Reported
	Allecet [Cetirizine Hydrochloride]			S		10 Mg, Unk		Not Reported
	Eltroxin			S		100 Ug, Unk		Not Reported

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Nexomist	S	150 Ug, Unk	Not Reported
Citraz	S	20 Mg, Unk	Not Reported
Proben [Ketoprofen]	S	500 Mg, Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	S	80 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>
14-Nov-2018	15618267	EXPEDITED (15-DAY)		HO, OT	GB-IMPAX LABORATORIES, LLC- 2018-IPXL-03755		39 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>	
Electrocardiogram Qrs Complex Shortened; Intentional Overdose; Loss Of Consciousness; Methaemoglobinaemia; Sinus Tachycardia	Chloroquine Phosphate			S	Unknown	2.5 Gram, Unk		Impax	
	Maloprim			S	Unknown	100 Milligram, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15618292	EXPEDITED (15-DAY)		OT	DE-IMPAX LABORATORIES, LLC- 2018-IPXL-03756			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>	
Intentional Overdose; Suicide Attempt	Chloroquine Phosphate			S	Oral	12.5 Gram, 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>
21-Nov-2018	15644851	EXPEDITED (15-DAY)		HO, OT	BE-IMPAX LABORATORIES, LLC- 2018-IPXL-03754		17 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Hypoxia; Cardiac Arrest; Cardiogenic Shock; Coma; Generalised Tonic- Clonic Seizure; Intentional Overdose; Pulseless Electrical Activity; Suicide	Chloroquine Phosphate			S	Oral	8 Gram, Single		Impax	

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Attempt

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2018	15646835	EXPEDITED (15-DAY)		HO, OT	CA-IPCA LABORATORIES LIMITED-IPC-2018-CA- 002323			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>	
Acute Kidney Injury; Bifascicular Block; Cardiac Failure; Cardiomyopathy; Toxicity To Various Agents	Chloroquine			S	Oral	250 Mg, Qd		Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15656999	EXPEDITED (15-DAY)		OT	ZA-SAKK- 2018SA148742AA			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>	
Carditis; Depression; Dyslipidaemia; Renal Disorder; Rheumatic Fever	Arava			S		20 Mg, Qd		Sanofi	
	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi	
	Minocycline Hydrochloride			S		60 Mg, Qd		Not Reported	
	Methotrexate Sodium			S		25 Mg, Qw		Not Reported	
	Azithromycin			S		75 Mg, Qd		Not Reported	
	Enbrel			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15661832	EXPEDITED (15-DAY)		HO, OT	CA-NATCO PHARMA- 2018NAT00149		45 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Bifascicular Block; Bradycardia; Cardiac Failure; Cardiomyopathy; Cardiotoxicity; Kidney Congestion; Mitral Valve	Chloroquine Phosphate			S	Oral	250 Mg, 1x/Day		Natco Pharma	

FDA Adverse Event Reporting System

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Detailed Report

Incompetence; Tricuspid
Valve Incompetence;
Ventricular Hypertrophy

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2018	14991271	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA143515		54 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>
Gastritis; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Methotrexate			S				Not Reported
	Salazopyrin			S		1 G, Bid		Not Reported
	Mycin [Benzathine Benzylpenicillin]			S		5 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15022906	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA150949		40 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>
Carditis; Dyslipidaemia	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi
	Etanercept			S		50 Mg, Qw		Not Reported
	Azithromycin			S		75 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15599369	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2018435066		61 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Malaise; Pain; Post Procedural Complication; Sensory Loss; Swelling;	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Sulfasalazine			S	Oral	Unk		Pfizer
	Arava			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported
	Plaquenil [Hydroxychloroquine]			S	Oral	Unk		Not Reported

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Therapeutic Product Effect Incomplete; Thrombosis		Phosphate] Remicade		S	Unk		Not Reported		
		Xeljanz		C	Oral		5 Mg, 2x/Day		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15668841	EXPEDITED (15-DAY)		OT	GB-IPCA LABORATORIES LIMITED-IPC-2018-GB- 002340			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelinating Polyneuropathy; Drug Interaction; Myopathy; Toxicity To Various Agents	Chloroquine			S	Unknown	Unk		Ipca	
	Mepacrine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15656996	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA152994		34 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>	
Haemoglobin Decreased; Psoriatic Arthropathy; Surgery	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg, Qd		Sanofi	
	Leflunomide			S	Unknown	20 Mg, Qd		Sanofi	
	Methotrexate Sodium			S	Unknown	25 Mg, Qw		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15183900	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA195262			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>	
Drug Ineffective; Interstitial Lung Disease	Chloroquine (Salt Not Specified)			S		150 G, Qd		Sanofi	
	Methotrexate			S				Not Reported	
	Salazopyrin			S		1 G, Bid		Not Reported	
	Azathioprine			S		100 Mg		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15682238	EXPEDITED (15-DAY)		OT	GB-NATCO PHARMA-2018NAT00150		48 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Neuromyopathy	Chloroquine Phosphate			S	Unknown	Unk		Natco Pharma	
	Chloroquine Phosphate			S	Unknown	Unk		Natco Pharma	
	Mepracrine			S	Unknown	Unk		Not Reported	
	Mepracrine			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-Dec-2018	12350349	NON-EXPEDITED			US-PFIZER INC-2016209168		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Prazosin Hcl			S		Unk		Pfizer	
	Boniva			S		Unk		Not Reported	
	Plaquenil			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Paxil [Paroxetine Hydrochloride]			S		Unk		Not Reported	
	Celexa			S		Unk		Not Reported	
	Savella			S		Unk		Not Reported	
	Catapres			S		Unk		Not Reported	
	Chloroquine			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>
05-Dec-2018	6461464	EXPEDITED (15-DAY)		HO	IT-AVENTIS-200715161EU		79 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Eczema	Lasix			S	Oral	250 Mg, Qd		Sanofi	
	Chloroquine Phosphate			S	Oral	400 Mg, Qd		Sanofi	

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Sartan		C		Dose As Used: Unk		Not Reported			
Ace Inhibitors		C		Dose As Used: Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2018	15696064	EXPEDITED (15-DAY)		OT	CA-IMPAX LABORATORIES, LLC- 2018-IPXL-04006		45 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Renal Failure; Restrictive Cardiomyopathy	Chloroquine Phosphate			S	Oral	250 Milligram, Daily		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>
07-Dec-2018	15700792	EXPEDITED (15-DAY)		OT	FR-SA-2018SA138087		32 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>	
Acquired Pigmented Retinopathy; Maculopathy; Visual Acuity Reduced	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Average Of 5.9 Mg/Kg/Day)		Sanofi	
	Chloroquine (Salt Not Specified)			S	Unknown	300 Mg, Qd(Average Of 4.4 Mg/Kg/Day)		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15704098	EXPEDITED (15-DAY)		OT	PHHY2015PL075992		25 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>	
Drug Ineffective; Maternal Exposure During Pregnancy; Off Label Use; Retroperitoneal Haemorrhage	Neoral			S	Unknown	200 Mg, Qd		Novartis	
	Neoral			S	Unknown	250 Mg, Qd		Novartis	
	Neoral			S	Unknown	200 Mg, Qd		Novartis	
	Deflazacorte			S	Oral	12 Mg, Qd		Not Reported	
	Methylprednisolone			S	Oral	20 Mg, Qd		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported	

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		Methylprednisolone		S	Unknown	Unk			Not Reported
		Chloroquine		S	Unknown	250 M, Qd			Not Reported
		Prednisone		C	Unknown	1 Mg/Kg, Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15704231	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018GSK214715		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>	
Anxiety; Aura; Cataract; Depression; Drug Ineffective; Dry Skin; Halo Vision; Pain; Pruritus; Rash	Benlysta Chloroquine			S S				Glaxosmithkline Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2018	15733642	EXPEDITED (15-DAY)		OT	HU-IPCA LABORATORIES LIMITED-IPC-2018-HU-002417			Unknown	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>	
Cardiomyopathy; Left Ventricular Dysfunction	Chloroquine			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>
19-Dec-2018	15741019	EXPEDITED (15-DAY)		HO, OT	IT-SA-2018SA106263		37 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Cardiomegaly; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea At Rest; Haemoptysis; Hypoxia; Lung Opacity; Oxygen Saturation Abnormal;	Chloroquine (Salt Not Specified)			S	Oral	10 Mg/Kg,Unk		Sanofi	
	Chloroquine (Salt Not Specified)			S	Oral	5 Mg/Kg,Unk		Sanofi	

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Pathogen Resistance;
Plasmodium Ovale
Infection; Pleural Effusion;
Pyrexia; Rales;
Respiratory Rate
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>
24-Dec-2018	15757513	EXPEDITED (15-DAY)		DE	IN-IMPAX LABORATORIES, LLC- 2018-IPXL-04309		12 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>
Respiratory Failure; Toxic Epidermal Necrolysis	Chloroquine Phosphate			S	Oral	Unk		Impax
	Divalproex Sodium Er			S	Unknown	300 Mg/ML, 1 /Day		Impax
	Lamotrigine Odt			S	Oral	50 Milligram, 1 /Day		Impax
	Cefixime Trihydrate W/Clavulanate Potassium			S	Oral	Unk		Not Reported
	Paracetamol			S	Oral	Unk		Not Reported
	Primaquine			S	Oral	Unk		Not Reported
	Clonazepam			S	Unknown	0.25 Mg/ML, 1 /Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15761291	EXPEDITED (15-DAY)		OT	PHHY2018DE194946		76 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Basal Cell Carcinoma	Methotrexate			S	Unknown	17.5 Mg, Qw		Novartis
	Chloroquine			S	Unknown	1 Mg/L, Qd		Not Reported
	Abatacept			S	Subcutaneous	125 Mg, Qw		Not Reported
	Quensyl			S	Unknown	1 Df, Qd		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Phenprocoumon			C	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	14959059	EXPEDITED (15-DAY)		DS, OT	FR-MYLANLABS-2018M1035289		32 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>	
Blindness; Maculopathy; Retinal Degeneration; Retinal Fovea Disorder; Retinopathy; Visual Acuity Reduced; Visual Field Defect; Visual Impairment	Hydroxychloroquine			S	Unknown	400 Mg, Qd (Receiving For 8 Years; Average Of 5.9 Mg/Kg/Day)		Not Reported	
	Chloroquine			S	Unknown	300 Mg, Qd (Receiving For 9 Years; Average Of 4.4 Mg/Kg/Day)		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>
20-Jan-2019	15846005	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2019AP006093		40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Completed Suicide	Amlodipine			S	Unknown			Apotex	
	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>
24-Jan-2019	15862174	EXPEDITED (15-DAY)		HO	FR-SA-2019SA016843		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram T Wave Abnormal; Malaise	Chloroquine (Salt Not Specified)			S	Oral	16 Df, Qd		Sanofi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15837001	EXPEDITED (15-DAY)		HO	BE-ROCHE-2244503		24 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Hypotension;	Diazepam			S	Unknown			Not Reported	
	Diazepam			S	Unknown			Not Reported	

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Sedation Complication; Stupor; Therapeutic Response Decreased; Toxicity To Various Agents	Diazepam	S	Unknown	1 Mg/Kg Continuous Infusion For 24 Hours	Not Reported
	Nivaquine	S	Oral	30-40 Tablets 100 Mg, 7.87 Ug/MI 1 X	Not Reported
	Nordiazepam	C	Unknown		Not Reported
	Tranxene	C	Unknown	3 Tablet Of Unknown Dosage	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jan-2019	15879658	NON-EXPEDITED			US-NATCO PHARMA- 2018NAT00125		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Nausea; Off Label Use	Chloroquine Phosphate			S	Oral	250 Mg, 1x/Day At Night		Natco Pharma	
	Buspar			C		15 Mg, 3x/Day		Not Reported	
	Plavix			C		75 Mg, 1x/Day		Not Reported	
	Topamax			C		300 Mg, 2x/Day		Not Reported	
	Viibryd			C		40 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896901	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2019040285		39 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>	
Drug Ineffective; Finger Deformity; Foot Deformity; Synovitis; Tuberculin Test Positive	Methotrexate Sodium			S	Subcutaneous	20 Mg, Unk		Pfizer	
	Chloroquine			S		200 Mg, Unk		Not Reported	
	Arava			S	Oral	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15736884	EXPEDITED (15-DAY)		OT	GB-IMPAX LABORATORIES, LLC- 2018-IPXL-04066		48 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Demyelinating	Chloroquine Phosphate	S	Unknown	Unk	Impax
Polyneuropathy; Drug Interaction; Myopathy; Toxicity To Various Agents	Mepacrine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15992822	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1016048		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Swelling; Weight Decreased	Chloroquine			S	Unknown	250 Milligram Daily;		Not Reported
	Methotrexate			S	Subcutaneous			Barr
	Apo-Leflunomide			S	Unknown	20 Milligram Daily;		Not Reported
	Arava			S	Oral	20 Milligram Daily;		Not Reported
	Enbrel			S	Unknown	20 Milligram Daily;		Not Reported
	Plaquenil			S	Unknown	250 Milligram Daily;		Not Reported
	Sulfasalazine			S	Unknown	2 Gram Daily;		Not Reported
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16011210	EXPEDITED (15-DAY)		OT	CA-ROCHE-2267275			Female	CAN

<u>Preferred Term</u>	<u>Product</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	2 Tablets		Not Reported
	Xeljanz			S	Oral	Ongoing: Yes		Not Reported
	Methotrexate			S	Oral	Discontinued		Not Reported
	Methotrexate			S	Subcutaneous	25 Mg/ML Various Dosages		Not Reported
	Champix			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Prednisone			C	Unknown	Ongoing: Yes		Not Reported

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

Folic Acid	C			Not Reported
Pantoprazole Magnesium	C	Unknown	Ongoing: Yes	Not Reported
Asaphen	C	Unknown	Q Unk	Not Reported
Synthroid	C	Unknown	Q Unk	Not Reported
Nasacort	C	Unknown	Q Unk	Not Reported
Warfarin Sodium	C	Oral	Q Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2019	12606526	EXPEDITED (15-DAY)		DE, HO, OT	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-061028		69 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>	
Breast Neoplasm; Cardiac Failure; Invasive Lobular Breast Carcinoma; Surgery	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Bristol Myers Squibb	
	Methotrexate			S	Unknown	2.5 Mg, Qwk		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported	
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported	
	Carvedilol			C	Unknown			Not Reported	
	Valsartan			C	Unknown			Not Reported	
	Acetylsalicylic Acid			C	Unknown			Not Reported	
	Quensyl			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Mar-2019	15739429	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018DE188813		69 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>	
Breast Neoplasm; Cardiac Failure; Invasive Lobular Breast Carcinoma; Myocardial Infarction	Methotrexate			S	Unknown	2.5 Mg, Qw		Novartis	
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	200 Mg, Qd		Not Reported	

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

Abatacept	S	Intravenous (not otherwise specified)	750 Mg, Q4w	Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Carvedilol	C	Unknown		Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Quensyl	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16082361	EXPEDITED (15-DAY)	HO		US-ROCHE-2281333		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Osteonecrosis; Skin Infection	Mycophenolate Mofetil			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Belimumab			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104684	EXPEDITED (15-DAY)	OT		ZA-ROCHE-2283269		44 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>
Bronchitis; Condition Aggravated; Drug Ineffective; Rheumatoid Arthritis	Actemra			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Unknown			Not Reported
	Revellex			S	Unknown			Not Reported
	Prednisolone			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Plasmoquine			S	Unknown			Not Reported

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

Salazopyrin	S	Unknown	Not Reported
Methotrexate	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16110766	EXPEDITED (15-DAY)		OT	CA-AMGEN- CANSP2019044504		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Primary Biliary Cholangitis; Psoriatic Arthropathy	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen
	Methotrexate			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	250 Milligram		Not Reported
	Leflunomide			S	Unknown	Unk		Not Reported
	Sulfasalazine			C		1 Gram, Bid		Not Reported
	Simponi			C		50 Milligram, Qmo		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported
	Xeljanz			C	Oral	5 Milligram, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	15893341	EXPEDITED (15-DAY)		DS	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201901- 000161		51 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Visual Acuity Reduced; Visual Impairment	Plaquenil 200 Mg Tablet			S	Oral			Concordia
	Nivaquine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126168	EXPEDITED (15-DAY)		OT	CO-SA-2019SA080512		69 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypoaesthesia; Limb Discomfort	Chloroquine (Salt Not Specified)			S				Sanofi
	Etanercept			S	Subcutaneous	50 Mg, Qw		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16134374	EXPEDITED (15-DAY)		OT	CA-SA-2017SA020135		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Synovitis	Hydroxychloroquine			S	Unknown	250 Mg,Unk		Sanofi	
	Chloroquine (Salt Not Specified)			S	Unknown	250 Mg,Unk		Sanofi	
	Arava			S		750 Mg,Unk		Sanofi	
	Xeljanz			S		5 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16148390	EXPEDITED (15-DAY)		OT	CA-SA-2019SA083762		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bursitis; Dizziness; Gastrointestinal Disorder; Headache; Irritability; Nausea; Perioral Dermatitis; Rash; Urticaria	Hydroxychloroquine Sulfate			S		400 Mg, Qw		Sanofi	
	Chloroquine (Salt Not Specified)			S		400 Mg, Qw		Sanofi	
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported	
	Methotrexate			S		10 Mg, Qd		Not Reported	
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported	
	Hydrocortisone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16155867	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA087152		40 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; Drug Intolerance; Maculopathy; Migraine; Peptic Ulcer	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi	
	Arava			S		20 Mg, Qd		Sanofi	
	Methotrexate			C		30 Mg, Qw		Not Reported	
	Salazopyrin			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16158821	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA087426			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>	
Ankylosing Spondylitis; Hla-B*27 Positive	Chloroquine (Salt Not Specified)			S		Unk		Sanofi	
	Arava			S		Unk		Sanofi	
	Methotrexate			C		Unk		Not Reported	
	Vimovo			C				Not Reported	
	Coxflam			C				Not Reported	
	Xefo			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Apr-2019	13234105	EXPEDITED (15-DAY)		OT	CA-CONCORDIA PHARMACEUTICALS INC.-GSH201702- 000981		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Synovitis	Hydroxychloroquine			S	Unknown			Concordia	
	Chloroquine			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Arava			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16162688	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA090683		27 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>	
Basedow'S Disease; Depression; Hypothyroidism; Obesity; Psoriasis	Chloroquine (Salt Not Specified)			S		Unk Unk, Qd		Sanofi	
	Methotrexate Sodium			C		25 Mg, Qw		Not Reported	
	Salazopyrin			C		1 G, Bid		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16169337	EXPEDITED (15-DAY)		OT	PT-FDC LIMITED-2065451		68 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Polyneuropathy	Ciprofloxacin			S	Unknown			Fdc	
	Naproxen			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>
11-Apr-2019	15478688	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018400947		45 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; Glucose Tolerance Impaired; Obesity; Rheumatoid Arthritis	Methotrexate Sodium			S	Intramuscular	30 Mg, Unk		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	
	Arava			S		20 Mg, Daily		Not Reported	
	Azathioprine			S		100 Mg, Daily		Not Reported	
	Endoxan [Cyclophosphamide Monohydrate]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	13048407	EXPEDITED (15-DAY)		OT	DE-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-105259		76 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma; Skin Neoplasm Excision	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb	
	Methotrexate			S	Unknown	17.5 Mg, Qwk		Not Reported	
	Quensyl			S	Unknown	1 Df, Qd		Not Reported	
	Chloroquine			S	Unknown	1 Df, Qd		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Phenprocoumon			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>
15-Apr-2019	16196019	EXPEDITED (15-DAY)		OT	ZA-CIPLA LTD.- 2019ZA01912			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>
Antinuclear Antibody Positive; Haematocrit Decreased; Neutrophil Count Decreased; Unevaluable Event; White Blood Cell Count Decreased	Coxflam			S	Unknown	15 Milligram, Daily		Cipla
	Nivaquine /00001001/			S	Unknown	200 Milligram, Daily		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Eltroxin			C	Unknown	Unk		Not Reported
	Zildem			C	Unknown	180 Milligram		Not Reported
	Alzam			C	Unknown	Unk		Not Reported
	Alzam			C				Not Reported
	Cipralex /01588501/			C	Unknown	Unk		Not Reported
	Cipralex /01588501/			C				Not Reported
	Lamictin			C	Unknown	Unk		Not Reported
	Lamictin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2019	15330499	EXPEDITED (15-DAY)		OT	ZA-SAKK- 2018SA222206AA			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>
Knee Deformity; Neutropenia; Osteoarthritis; Pneumonia; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg, Unk		Sanofi
	Arava			S	Unknown	20 Mg, 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>
30-Apr-2019	16253964	EXPEDITED (15-DAY)		OT	ZA-BAXTER- 2019BAX008072		45 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>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Depression; Glucose Tolerance Impaired; Obesity; Rheumatoid Arthritis	Endoxan Vial 1g	S	Unknown	Baxter
	Methotrexate	S	Unknown	Not Reported
	Chloroquine	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Azathioprine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	15808456	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019011051		76 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma	No Subject Drug			S		No Dose Given		Not Reported	
	Methotrexate Sodium			S	Unknown	17.5 Mg, Qwk		Pfizer	
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Not Reported	
	Chloroquine			S	Unknown	1 Df/400mg, Qd		Not Reported	
	Quensyl			S	Unknown	400 Mg, 1x/Day (1 Df, Qd, 1df = 400mg)		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Phenprocoumon			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	11515767	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015288282		37 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Product Use Issue; Rheumatoid Arthritis; Swelling; Weight Decreased	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Enbrel			S	Unknown	20 Mg, 1x/Day		Pfizer	
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown	
	Sulfasalazine			S		1 G, 2x/Day		Pfizer	
	Sulfasalazine			S	Unknown	500 Mg, 2x/Day		Pfizer	
	Plaquenil			S	Unknown	250 Mg, 1x/Day		Not Reported	
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported	

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Chloroquine	S	Unknown	250 Mg, 1x/Day	Not Reported
Leflunomide	S		20 Mg, Once Daily	Not Reported
Apo-Leflunomide	S	Unknown	20 Milligram	Not Reported
Apo-Leflunomide	S	Unknown	20 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	12340586	EXPEDITED (15-DAY)		OT	CA-AMGEN-CANSP2015089393		37 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Fall; Hypoacusis; Nausea; Pain; Product Use Issue; Rheumatoid Arthritis; Swelling; Weight Decreased	Enbrel			S	Unknown	20 Milligram, Qd		Amgen
	Leflunomide			S	Unknown	20 Mg, Once Daily		Not Reported
	Arava			S	Oral	20 Milligram, Qd		Not Reported
	Chloroquine			S	Unknown	250 Milligram, Qd		Not Reported
	Methotrexate Sodium			S	Subcutaneous	25 Milligram, Qwk		Not Reported
	Plaquenil			S	Unknown	250 Mg, Qd		Not Reported
	Sulfasalazine			S	Unknown	1 G, Twice Daily		Not Reported
	Sulfasalazine			S	Unknown	500 Mg, Unk		Not Reported
	Xeljanz			S	Oral	5 Milligram, Bid		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram		Not Reported
	Apo-Leflunomide			S	Unknown	20 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16253633	EXPEDITED (15-DAY)		OT	CO-ABBVIE-19K-036-2763123-00		38 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ankylosing Spondylitis; Blindness	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous	Humira Ac		Not Reported
	Chloroquine			S	Unknown			Not Reported
	Cefalexin			C				Not Reported
	Prednisolone			C	Unknown			Not Reported

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	Metotrexato	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Acetaminophen	C		Not Reported
	Diclofenac	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	15703425	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018- 3621		88 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>
Dyspnoea; Rash; Retinal Pigment Epitheliopathy; Synovitis	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Chloroquine Hydrochloride			S	Unknown			Not Reported
	Cellcept			C	Unknown			Not Reported
	Prograf			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Depo-Medrol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16364062	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2019221583		79 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>
Arthritis; Drug Ineffective; Hla-B*27 Positive	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Salazopyrin			S		2 G, Daily		Pfizer
	Chloroquine			S		200 Mg, Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Mypaid			C		2-3 Tablets, Daily		Not Reported
	Ziak			C				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16417334	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2019M1053931		76 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma	Methotrexate			S	Unknown	17.5 Mg, Qwk		Not Reported	
	Quensyl			S	Unknown	1 Df, Qd		Mylan	
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Mylan	
	Chloroquine			S	Unknown	1 Df, Qd		Mylan	
	Folic Acid			C	Unknown	Unk		Mylan	
	Phenprocoumon			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	14559053	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2018068177		64 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>	
Blood Creatine Increased; Drug Ineffective; Haemoglobin Decreased; White Blood Cell Count Decreased	Salazopyrin			S	Oral	15 G, 2x/Day		Pfizer	
	Chloroquine			S	Oral	200 Ug, Daily		Not Reported	
	Enbrel			C	Subcutaneous	50 Mg, Weekly		Not Reported	
	Pritor /01102601/			C		80 Ug, Daily		Not Reported	
	Protos /00737201/			C		2 G, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16425203	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2019M1054106		68 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>	
Anxiety; Dizziness; Drug Interaction; Neuropathy Peripheral; Tremor	Ciprofloxacin			S		500 Mg, Bid		Not Reported	
	Ciprofloxacin			S				Not Reported	
	Chloroquine			S		Unk		Mylan	
	Indometacin			S		Unk		Mylan	

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Indometacin			S			Unk			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16443758	EXPEDITED (15-DAY)		DE, OT	ES-ROCHE-2337190		76 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Completed Suicide; Intentional Product Misuse; Overdose	Diazepam			S	Unknown	0.12 Mg/DI		Not Reported		
	Chloroquine Phosphate			S	Unknown	18 Mg/DI		Not Reported		
	Metoclopramide Hydrochloride			S	Unknown			Not Reported		
	Lorazepam			S	Unknown	0.25 Mg/DI		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Jun-2019	16456352	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2019259297		59 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>		
Drug Ineffective; Haemoglobin Decreased; Synovitis; White Blood Cell Count Decreased	Methotrexate Sodium			S		20 Mg, Weekly		Pfizer		
	Salazopyrin			S		1.5 G, 2x/Day		Pfizer		
	Chloroquine			S		200 Mg, Mon-Fri		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2019	16088792	EXPEDITED (15-DAY)		OT	CO-AMGEN- COLSP2019042806		69 YR	Female	COL	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Diabetes Mellitus; Hypoaesthesia; Limb Discomfort	Enbrel			S	Subcutaneous	50 Milligram, Qwk		Amgen		
	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>	
03-Jul-2019	16523490	EXPEDITED (15-DAY)		OT	PL-ROCHE-2346668		58 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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Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Rituximab	S	Unknown		Not Reported
	Tocilizumab	S	Unknown		Not Reported
	Hydroxychloroquine	S	Unknown		Not Reported
	Chloroquine	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Infliximab	S	Unknown		Not Reported
	Methylprednisolone	C	Unknown	Up To 32 Mg	Not Reported
	Venlafaxine	C	Unknown	Dose: 75 Mg/D	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16575363	EXPEDITED (15-DAY)		OT	PHHY2019PL160571		58 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>
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Rituximab			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	25 Mg, Qw		Novartis
	Tocilizumab			S	Unknown	Unk		Not Reported
	Infliximab			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Venlafaxine			C	Unknown	75 Mg/DI, Unk		Not Reported
	Methylprednisolone			C	Unknown	Upto 32 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577427	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2019299169			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>
Arthralgia; Arthropathy; Immobile; Musculoskeletal Pain; Musculoskeletal Stiffness; Overweight; Plantar Fasciitis; Rotator	Methotrexate Sodium			S		20 Mg, Unk		Pfizer
	Chloroquine			S		3 Days A Week		Not Reported
	Prednisone			S		5 Mg, 1x/Day		Not Reported
	Humira			S		40 Unk, Unk		Not Reported

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Cuff Syndrome; Tendonitis		Folic Acid		C		5 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16590505	EXPEDITED (15-DAY)		HO, OT	ZA-PFIZER INC-2019299922			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>	
Anaemia Of Chronic Disease; Drug Ineffective; Joint Range Of Motion Decreased; Magnetic Resonance Imaging Spinal Abnormal	Salazopyrin			S		1 G, 2x/Day		Pfizer	
	Methotrexate			S		20 Mg, Weekly		Pfizer	
	Chloroquine			S		200 Mg, (Monday To Friday)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2019	15252264	EXPEDITED (15-DAY)		HO, LT	NL-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2018-12-00		27 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>	
Cardiac Arrest; Hypokalaemia; Intentional Overdose; Suicide Attempt	Catapresan			S	Unknown			Boehringer Ingelheim	
	Flurazepam			S	Unknown			Not Reported	
	Dextroamphetamine			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>
19-Jul-2019	16600055	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2019302000		58 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>	
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Infliximab Hospira			S		Unk		Not Reported	
	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer	
	Tocilizumab			S		Unk		Not Reported	
	Rituximab			S		Unk		Not Reported	
	Hydroxychloroquine			S		Unk		Not Reported	

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Chloroquine	S	Unk	Not Reported
Venlafaxine	C	Dose: 75 Mg/D	Not Reported
Methylprednisolone	C	Up To 32 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16610192	EXPEDITED (15-DAY)		OT	PL-JNJFOC-20190713697		58 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>	
Blood Glucose Increased; Depression; Diabetes Mellitus Inadequate Control; Infection; Type 2 Diabetes Mellitus	Infliximab, Recombinant Solution For Infusion			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Tocilizumab			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Venlafaxine			C	Unknown	Dose: 75 Mg/D		Not Reported	
	Methylprednisolone			C	Unknown	Up To 32 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	14152913	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017467944		21 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>	
Cachexia; Drug Ineffective; Gastroesophageal Reflux Disease; Hepatic Steatosis; Hypersensitivity	Methotrexate Sodium			S	Subcutaneous	30 Ug, Weekly		Unknown	
	Salazopyrin			S		1 G, Twice A Day		Pfizer	
	Plasmaquine			S		200 Ug, Daily		Not Reported	
	Arava			S		20 Ug, Daily		Not Reported	
	Enbrel			C	Subcutaneous	50 Mg, Weekly		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2019	16644805	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019319293		49 YR	Female	ZAF

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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>
Polyarthrititis	Methotrexate			S		20		Pfizer
	Salazopyrin			S		3 G, Unk		Pfizer
	Chloroquine			S		2000		Not Reported
	Prednisolone			S		On And Off		Not Reported
	Arava			S		20		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2019	16305935	EXPEDITED (15-DAY)		DE, HO, OT	DE-MYLANLABS-2019M1044234		69 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>
Breast Neoplasm; Cardiac Failure; Invasive Lobular Breast Carcinoma; Myocardial Infarction	Methotrexate			S	Unknown	2.5 Milligram, Qw (2.5 Mg, Qwk)		Not Reported
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd (400 Mg, Qd)		Mylan
	Hydroxychloroquine			S	Unknown	200 Milligram, Qd (200 Mg, Qd)		Mylan
	Chloroquine			S	Unknown	200 Milligram, Qd (200 Mg, Qd)		Mylan
	Abatacept			S	Intravenous (not otherwise specified)	750 Mg, Q4wk		Mylan
	Acetylsalicylic Acid			C	Unknown	Unk		Mylan
	Carvedilol			C	Unknown	Unk		Mylan
	Valsartan			C	Unknown	Unk		Mylan
	Quensyl			C	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16054264	EXPEDITED (15-DAY)		HO	DE-ABBVIE-19K-062-2668618-00		67 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>
Foot Deformity	Humira			S	Subcutaneous			Not Reported

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	Chloroquine Phosphate\Hydroxychloroquine Sulfate\Quinacrine Hydrochloride		S	Unknown					Not Reported
	Chloroquine Phosphate\Hydroxychloroquine Sulfate\Quinacrine Hydrochloride		S	Unknown	Between 2012 And 2013				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2019	16682838	EXPEDITED (15-DAY)		OT	PHHY2019US179546		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maculopathy; Retinal Injury	Hydroxychloroquine			S	Unknown			Novartis	
	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-Aug-2019	15991568	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC- 2019074358		61 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>	
Dural Tear; Dysphagia; Oesophagitis; Sinusitis	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer	
	Methotrexate			S	Unknown	25 Mg, Unk		Pfizer	
	Plasmoquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16713470	EXPEDITED (15-DAY)		HO	CA-TEVA-2019-CA- 1092241		61 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy; Bone Pain; Diarrhoea; Gait Disturbance; Hypoaesthesia; Malaise; Pain; Post Procedural Complication; Sensory	Chloroquine			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Barr	
	Arava			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	

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Loss; Swelling;	Remicade	S	Unknown	Not Reported
Therapeutic Product Effect	Sulfasalazine	S	Oral	Not Reported
Incomplete; Thrombosis	Xeljanz	C	Oral	Not Reported
			10 Milligram Daily;	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16717734	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA218786			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>
Polyarthrititis	Arava			S	Unknown	Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	Unk		Sanofi
	Methotrexate			C	Unknown	Unk		Not Reported
	Salazopyrin			C		3 G		Not Reported
	Prednisone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15771228	EXPEDITED (15-DAY)		DS	ZA-PFIZER INC-2018530431		21 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>
Blood Creatinine	Methotrexate			S		25 Mg, Weekly		Pfizer
Decreased; Treatment	Methotrexate			S		10 Mg, Weekly		Pfizer
Failure; Wheelchair User	Salazopyrin			S		200 Mg, Unk		Pfizer
	Chloroquine			S		1.5 G, 2x/Day		Not Reported
	Arava			S		20 Mg, Unk		Not Reported
	Cyclosporin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	14186780	NON-EXPEDITED		OT	CA-AMGEN-CANSP2017170122		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Enbrel			S	Unknown	20 Milligram, Qd		Amgen

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Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Arava	S	Oral	20 Milligram, Qd	Not Reported
	Chloroquine	S	Unknown	250 Milligram, Qd	Not Reported
	Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported
	Methotrexate Sodium	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Plaquenil	S	Unknown	250 Milligram, Qd	Not Reported
	Sulfasalazine	S	Unknown	1 Gram, Bid	Not Reported
	Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
	Methotrexate	S	Subcutaneous	25 Milligram, Qwk	Not Reported
	Apo-Leflunomide	S	Unknown	20 Milligram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	14195502	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2017491606		38 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Fall; Feeling Abnormal; Hypoacusis; Nausea; Pain; Rheumatoid Arthritis; Swelling; Weight Decreased	Enbrel			S	Unknown	20 Mg, Qd		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Qwk		Unknown
	Sulfasalazine			S	Unknown	1 G, Bid		Pfizer
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer
	Arava			S	Oral	20 Mg, Qd		Not Reported
	Chloroquine			S	Unknown	250 Mg, Qd		Not Reported
	Leflunomide			S	Unknown	20 Mg, Qd		Not Reported
	Plaquenil			S	Unknown	250 Mg, Qd		Not Reported
	Apo-Leflunomide			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>
21-Aug-2019	15916366	NON-EXPEDITED		OT	BR-AMGEN- BRASP2019016503		55 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>
Arthralgia; Limb Discomfort; Pain; Pain In	Enbrel			S	Unknown	Unk		Amgen
	Enbrel			S	Unknown	Unk		Amgen

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Extremity; Rheumatoid Arthritis; Visual Impairment		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>
21-Aug-2019	15998799	NON-EXPEDITED		HO, OT	ZA-AMGEN-ZAFSP2019028779		61 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>	
Dural Tear; Dysphagia; Oesophagitis; Sinusitis	Enbrel			S	Subcutaneous	25 Milligram, 2 Times/Wk		Amgen	
	Methotrexate			S	Unknown	25 Milligram		Not Reported	
	Plasmoquine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16734025	NON-EXPEDITED			US-ALLERGAN-1857322US		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Visual Impairment	Celexa			S	Unknown	Unknown		Allergan	
	Chloroquine			S	Unknown	Unknown		Not Reported	
	Savella			C				Not Reported	
	Catapres			C				Not Reported	
	Prazosin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2019	16763523	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019373918		31 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Ineffective; Joint Swelling	Methotrexate Sodium			S	Unknown	20 Mg, Weekly		Pfizer	
	Chloroquine			S	Unknown	Unk		Not Reported	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Amitriptyline			C		150 Mg, 1x/Day		Not Reported	
	Folate			C		5 Mg, 1 Every 2 Day (S)		Not Reported	
	Pariet			C		20 Mg, 2 Every 1 Day (S)		Not Reported	

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Vimovo			C		Unk, 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>
04-Sep-2019	16770896	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 3192		31 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Drug Ineffective; Joint Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Amitriptyline			C	Unknown			Not Reported	
	Folate			C	Unknown			Not Reported	
	Pariet			C	Unknown			Not Reported	
	Vimovo			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Sep-2019	16790458	EXPEDITED (15-DAY)		OT	ZA-SA-2019SA005382			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>	
Blood Creatinine Decreased; C-Reactive Protein Increased; Disease Progression; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Arthritis; Wheelchair User	Arava			S	Unknown	20 Mg, Qd		Sanofi	
	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi	
	Cyclosporin A			C				Not Reported	
	Rituximab			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2019	16795345	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019384712		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cataract; Off Label Use	Methotrexate Sodium	S	Subcutaneous	0.9 MI, 1 Every 1 Week	Unknown
	Chloroquine	S	Unknown	Unk Unk, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16795357	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019384724		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 Sodium			S	Unknown	Unk		Pfizer
Aggravated; Diverticulitis;	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
H1n1 Influenza; Hepatic	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
Enzyme Increased;	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
Hepatomegaly;	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
Palpitations; Pneumonia;	Belimumab			S	Unknown	900.0 Mg, Unk		Not Reported
Renal Disorder; Tooth	Chloroquine Diphosphate			S	Unknown	Unk		Not Reported
Extraction; Tooth Infection	Plaquenil S			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	15523354	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-963660		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Porphyria Non-Acute;	Tamoxifen			S	Unknown			Actavis
Vitiligo	Chloroquine			S	Oral			Not Reported
	Chloroquine			S	Oral			Not Reported
	Levothyroxine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16803764	EXPEDITED (15-DAY)		HO, OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-3334		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 (Trade Name)			S	Unknown			Not Reported

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Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth Extraction; Tooth Infection	Unknown) Belimumab Chloroquine Diphosphate Plaquenil S	S S S	Unknown Unknown Unknown	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>
17-Sep-2019	15235010	EXPEDITED (15-DAY)		HO, OT	NL-IPCA LABORATORIES LIMITED-IPC-2018-NL- 001562			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>
Cardiac Arrest; Electrocardiogram Qrs Complex Prolonged; Hypokalaemia; Intentional Overdose; Suicide Attempt; Toxic Encephalopathy; Toxicity To Various Agents	Chloroquine Clonidine Dextroamphetamine Flurazepam Promethazine			S S S S S	Oral Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk		Ipca Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	15292230	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR- APL-2018-042424		27 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>
Cardiac Arrest; Circulatory Collapse; Electrocardiogram Qrs Complex Prolonged; Hypokalaemia; Intentional Overdose; Pulseless Electrical Activity; Suicide Attempt; Toxic Encephalopathy	Clonidine Flurazepam Chloroquine Dextroamphetamine Promethazine			S S S S C	Unknown Oral Unknown Unknown Unknown	Unk Unk Unk Unk Unk		Aurobindo Aurobindo 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>
20-Sep-2019	14019756	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017413855		54 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>	
Chronic Kidney Disease; Drug Ineffective; Gastroesophageal Reflux Disease; Hypertension; Hypothyroidism; Maculopathy; Marfan'S Syndrome; Osteoporotic Fracture; Sinusitis; Underdose	Methotrexate			S		20 Ug, Weekly		Pfizer	
	Methotrexate			S		10 Mg, Unk		Pfizer	
	Chloroquine			S		200 Ug, Daily		Not Reported	
	Arava			C		20 Ug, Daily		Not Reported	
	Endoxan [Cyclophosphamide]			C		100 Ug, Daily		Not Reported	
	Enbrel			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831274	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2931350-00			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Chloroquine			S	Oral			Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	14240509	EXPEDITED (15-DAY)		OT	ZA-SA-2017SA231386		39 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>	
Drug Ineffective; Nephrolithiasis; Rheumatoid Arthritis	Arava			S	Oral	20 Mg,Qd		Sanofi	
	Chloroquine Sulfate			S	Unknown	Unk Unk,Unk		Sanofi	
	Sulfasalazine			S	Unknown	2 G,Qd		Not Reported	
	Methotrexate			S	Subcutaneous	25 Mg,Qw		Not Reported	

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		Prednisone		S	Unknown	Unk Unk,Unk			Not Reported
		Enbrel		S	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>
25-Sep-2019	16848584	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP022189		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Porphyria Non-Acute; Vitiligo	Tamioxifen			S	Unknown	Unk		Apotex	
	Chloroquine			S	Oral	125 Mg, Q.O.Wk		Not Reported	
	Chloroquine			S	Oral	250 Mg, Qd		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16348296	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018503098		88 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>	
Dyspnoea; Rash; Retinal Pigment Epitheliopathy; Synovitis	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Aralen			S	Unknown	Unk		Not Reported	
	Imuran			S	Unknown	Unk		Not Reported	
	Chloroquine Hydrochloride			S	Unknown	Unk		Not Reported	
	Chloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Cellcept			C		Unk		Not Reported	
	Prograf			C		Unk		Not Reported	
	Prednisone			C		5 Mg, Unk		Not Reported	
	Prednisone			C		10 Mg, Unk		Not Reported	
	Depo-Medrol			C		80 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877040	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019420142			Female	ZAF

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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>
Cushing'S Syndrome;	Methotrexate Sodium			S		25 Mg, Unk		Pfizer
Drug Ineffective;	Salazopyrin			S		1 G, 2x/Day		Pfizer
Lipohypertrophy;	Chloroquine			S		Unk		Not Reported
Osteonecrosis	Arava			S		Unk		Not Reported
	Medrol [Methylprednisolone Acetate]			C		8 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>
09-Oct-2019	12392584	NON-EXPEDITED		HO, OT	BR-AMGEN- BRASP2013037734		68 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 Distension;	Enbrel			S	Subcutaneous	50 Mg, 1x/Week		Amgen
Abdominal Pain;	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen
Abdominal Pain Upper;	Enbrel			S	Unknown	Unk Unk, Weekly		Amgen
Agitation; Alopecia;	Reuquinol			S	Unknown	Unk		Not Reported
Arthralgia; Arthritis;	Reuquinol			S				Not Reported
Asphyxia; Back Pain; Back	Chloroquine			S	Unknown	Unk		Not Reported
Pain; Blister; Blood	Synthroid			C		75 Milligram, 1x/Day		Not Reported
Pressure Decreased;	Synthroid			C		75 Mg, 1x/Day		Not Reported
Cataract; Cataract;	Omeprazol			C		20 Milligram, 1x/Day		Not Reported
Condition Aggravated;	Omeprazol			C		25 Milligram, 1x/Day		Not Reported
Condition Aggravated;	Omeprazol			C		20 Mg, 1x/Day		Not Reported
Decreased Appetite;	Omeprazol			C		25 Mg, 1x/Day		Not Reported
Depressed Mood;	Addera D3			C		Unk		Not Reported
Diarrhoea; Drug	Addera D3			C		Unk		Not Reported
Ineffective; Eating	Hydroxychloroquine			C		400 Milligram, 1x/Day		Not Reported
Disorder; Erythema; Fall;	Hydroxychloroquine			C		400 Mg, 1x/Day		Not Reported
Feeling Abnormal; Feeling	Predsim			C		5 Milligram,1x/Day		Not Reported
Abnormal; Gait Inability;	Predsim			C		5 Mg, 1x/Day		Not Reported
Gastrooesophageal Reflux								
Disease; Hernia;								
Hypertension; Influenza;								
Injection Site Induration;								
Injection Site Pain; Joint								
Swelling; Musculoskeletal								
Stiffness; Myopia; Pain;								
Pain In Extremity;								

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Peripheral Swelling; Pyrexia; Rheumatoid Arthritis; Rheumatoid	Zylum	C	1 Tablet Of 300 Milligram, Once Daily	Not Reported
Arthritis; Splenomegaly; Swelling; Swelling;	Zylum	C	1 Tablet Of 300 Mg, Once Daily	Not Reported
Syncope; Tooth Disorder; Visual Impairment; Visual	Methotrexate	C	15 Milligram, Once Weekly	Not Reported
Impairment; Weight Decreased; Weight	Methotrexate	C	15 Mg, Once Weekly	Not Reported
Increased; Wrong Technique In Device	Folic Acid	C	5 Milligram, Once Weekly	Not Reported
Usage Process; Wrong Technique In Product	Folic Acid	C	5 Mg, Once Weekly	Not Reported
Usage Process	Ranitidine	C	300 Milligram, 1x/Day	Not Reported
	Ranitidine	C	300 Mg, 1x/Day	Not Reported
	Cortisone	C	One Tablet Of 20 Milligram	Not Reported
	Cortisone	C	2 Tablets Of 5milligram (10 Milligram), Daily	Not Reported
	Cortisone	C	One Tablet Of 20 Mg, Unk	Not Reported
	Cortisone	C	2 Tablets Of 5mg (10 Mg), Daily	Not Reported
	Esomex	C	Unk	Not Reported
	Prednisone	C	Unk	Not Reported
	Valium	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897968	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019429983			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Methotrexate Sodium			S	Oral	10 Mg, Weekly		Pfizer	
	Methotrexate Sodium			S	Unknown	25 Mg, Weekly		Pfizer	
	Chloroquine			S	Oral	400 Mg, Daily		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk		Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown	Unk		Not Reported	
	Prednisone			C	Oral	7 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16906558	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 4143			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthrititis	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Methotrexate (Trade Name Unknown)			S	Oral			Not Reported	
	Chloroquine			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16907404	EXPEDITED (15-DAY)		OT	CA-ROCHE-2426901			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Synovitis	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Chloroquine Diphosphate			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Enbrel			C	Unknown			Not Reported	
	Methotrexate			C	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16913620	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019436261		32 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>	
Fatigue; Nasopharyngitis; Product Dose Omission; Productive Cough; Pyrexia; Respiratory Tract Infection; Sinus Congestion; Sputum Discoloured	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Belimumab			S	Unknown	Unk		Not Reported	
	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>
15-Oct-2019	16917457	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019- 4260		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	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Belimumab			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>
16-Oct-2019	16361088	EXPEDITED (15-DAY)		OT	PL-PFIZER INC- 2019217900		13 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>	
Steroid Diabetes	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)			Pfizer	
	Prednisone			S	Oral			Not Reported	
	Cyclosporine A			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>
16-Oct-2019	16925401	EXPEDITED (15-DAY)		HO, OT	US- GLAXOSMITHKLINE- US2019AMR185029			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neoplasm Malignant	Belimumab Subcutaneous			S	Unknown	Unk		Glaxosmithkline
	Plaquenil			S	Unknown	Unk		Not Reported
	Aralen			S	Unknown	Unk		Not Reported
	Atabrine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16934485	EXPEDITED (15-DAY)		OT	NVSC2019AR002296		44 YR	Female	ARG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Leukopenia; Product Use In Unapproved Indication; Rash; Subacute Cutaneous Lupus Erythematosis	Prednisolone			S	Unknown	Unk		Novartis
	Prednisone			S	Unknown	10 Mg, Qd		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	15 Mg, Qw		Not Reported
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16934756	EXPEDITED (15-DAY)		OT	NVSC2019CA004271			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			Novartis
	Leflunomide			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Myochrysine			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Humira			S	Unknown	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2019	16938916	EXPEDITED (15-DAY)		OT	NVSC2019CA004301			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Polyarthritits; Skin Lesion; Treatment Failure; Uveitis	Leflunomide			S	Unknown	Unk		Not Reported	
	Methotrexate Sodium			S	Unknown	Unk		Novartis	
	Aralen			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Myocrisne			S	Unknown	Unk		Not Reported	
	Remicade			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2019	16968039	EXPEDITED (15-DAY)		OT	NVSC2019CA016408			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritits; Skin Lesion; Uveitis	Methotrexate			S	Unknown	Unk		Novartis	
	Leflunomide			S	Unknown	Unk		Not Reported	
	Aralen			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Myochrysine			S	Unknown	Unk		Not Reported	
	Remicade			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2019	16973112	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-04797		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maculopathy	Hydroxychloroquine			S	Unknown	Unk		Lupin	

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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>
30-Oct-2019	16974479	EXPEDITED (15-DAY)		OT	CA-ROCHE-2444562		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	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Prednisone			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	
	Methylprednisolon [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>
31-Oct-2019	13984019	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017396341		49 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>	
Deep Vein Thrombosis; Drug Ineffective; Hypertension; Migraine; Mitral Valve Prolapse	Methotrexate			S		25 Mg, Weekly		Pfizer	
	Chloroquine			S		200 Mg, Daily		Not Reported	

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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>
01-Nov-2019	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 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
	Chloroquine			S	Unknown	250 Milligram Daily;		Not Reported
	Prednisone			S	Unknown	1 Dosage Forms Daily;		Actavis
	Cellcept			S	Oral	3 Milligram Daily;		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Rituxan			S	Intravenous (not otherwise specified)			Not Reported
	Mycophenolate Mofetil			S	Oral	3 Milligram Daily;		Teva
	Acetaminophen			C	Oral			Not Reported
	Actonel			C	Unknown			Not Reported
	Amlodipine			C				Not Reported
	Diphenhydramine			C	Oral			Not Reported
	Ferrous Gluconate			C	Unknown			Not Reported
	Losec			C				Not Reported
Medrol			C				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>
01-Nov-2019	16985102	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1129105			Female	CAN

<u>Preferred Term</u>	<u>Product</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;	Mycophenolate Mofetil			S	Unknown	2000 Milligram Daily;		Teva
	Azathioprine			S	Unknown			Not Reported

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Rash; Retinal Toxicity; Vomiting	Chloroquine	S	Unknown		Not Reported
	Methotrexate	S	Oral		Barr
	Methotrexate	S	Subcutaneous		Barr
	Varenicline Tartrate	S	Unknown		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	Unknown	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>
04-Nov-2019	16986887	EXPEDITED (15-DAY)		DE, OT	RU-ROCHE-2456384		67 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angiopathy; Death; Pneumonia; Respiratory Failure	Tocilizumab			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Abatacept			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2019	17014319	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1133109			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Juvenile Idiopathic Arthritis; Polyarthritis	Methotrexate			S	Unknown			Barr	
	Methotrexate			S	Oral			Barr	
	Chloroquine			S	Oral	400 Milligram Daily;		Not Reported	

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		Humira	S	Subcutaneous				Not Reported	
		Hydroxychloroquine Sulfate	S	Unknown				Not Reported	
		Prednisone	C	Oral	7 Milligram Daily;			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	17015238	EXPEDITED (15-DAY)		OT	ZA-TEVA-2019-ZA-1134260			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>	
Malignant Melanoma	Abitrexate			S	Oral			Barr	
	Plasmoquine			S	Unknown			Not Reported	
	Enbrel			S	Unknown	Every 2 Weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	17017454	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1133112		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Primary Biliary Cholangitis; Psoriatic Arthropathy	Chloroquine			S	Unknown			Not Reported	
	Leflunomide			S	Unknown			Barr	
	Methotrexate			S	Unknown			Barr	
	Enbrel			S	Subcutaneous			Not Reported	
	Simponi			C				Not Reported	
	Sulfasalazine			C		2 Gram Daily;		Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	
	Xeljanz			C	Oral	10 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	17017466	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1133117		88 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>	
Dyspnoea; Rash; Retinal Pigment Epitheliopathy	Chloroquine Hydrochloride			S	Unknown			Not Reported	

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Methotrexate	S	Unknown	Barr
Enbrel	S	Unknown	Not Reported
Imuran	S	Unknown	Not Reported
Cellcept	C	Unknown	Not Reported
Depo-Medrol	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported
Prograf	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Nov-2019	17017467	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1133119			Male	CAN

<u>Preferred Term</u>	<u>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
	Azathioprine			S	Oral			Not Reported
	Leflunomide			S	Oral			Barr
	Methotrexate			S	Unknown			Barr
	Methotrexate			S	Oral			Barr
	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>
12-Nov-2019	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
	Salazopyrin			C	Unknown	2 Mg, Qd		Not Reported
	Etanercept			C	Subcutaneous	50 Mg, Qw		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17031292	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019486581			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>	
Crohn'S Disease	Methotrexate Sodium			S		Unk		Pfizer	
	Salazopyrin			S		Unk		Pfizer	
	Plasmoquine			S				Not Reported	
	Arava			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17032186	EXPEDITED (15-DAY)		DE, OT	ES-MYLANLABS-2019M1109114		76 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Abuse; Intentional Product Misuse; Medication Error; Overdose	Diazepam			S		0.12 Milligram Per Decilitre		Not Reported	
	Lorazepam			S		5 One-Dose, 0.25 Mg/Dl		Not Reported	
	Chloroquine Phosphate			S		Box (5 Blisters Of 10 Mg Tablets Each), 18 Mg/Dl		Mylan	
	Metoclopramide Hydrochloride			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17032196	EXPEDITED (15-DAY)		DE, OT	ES-MYLANLABS-2019M1109109		34 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Drug Abuse; Intentional Product Misuse; Medication Error; Overdose; Toxicity To Various Agents	Diazepam			S	Unknown	Unk Unk, Unk		Not Reported	
	Lorazepam			S	Unknown	Unk Unk, Unk		Not Reported	
	Metoclopramide Hydrochloride			S	Unknown	Unk Unk, Unk		Mylan	
	Chloroquine Phosphate			S	Unknown	5 Blisters Of 10 Tablets Each (Around 50 Tablets)		Mylan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17047788	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019494849		6 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>	
Condition Aggravated; Polyarthrititis; Varicella Virus Test Positive	Methotrexate Sodium			S		10 Mg, Unk		Pfizer	
	Azathioprine			S		25 Mg, Daily Stat		Not Reported	
	Chloroquine			S		100 Mg, Unk		Not Reported	
	Prednisone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2019	17058439	EXPEDITED (15-DAY)		OT	SE-PFIZER INC-2019497678		68 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>	
Anxiety; Decreased Vibratory Sense; Dizziness; Drug Interaction; Erythema; Nerve Degeneration; Pain In Extremity; Peripheral Swelling; Polyneuropathy; Syncope; Systemic Lupus Erythematosus; Toxicity To Various Agents; Tremor	Ciprofloxacin Hcl			S		500 Mg, 2x/Day (Bid Was Initiated)		Unknown	
	Chloroquine			S		250 Mg, Daily (More Than Five Years)		Not Reported	
	Chloroquine			S				Not Reported	
	Indomethacin [Indometacin]			S		Unk		Not Reported	
	Indomethacin [Indometacin]			S		Unk		Not Reported	
	Naproxen			S		500 Mg, 2x/Day (Bid Was Continued)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2019	17115220	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019523307		42 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>	
Pulmonary Mass; Treatment Failure	Methotrexate Sodium			S				Pfizer	
	Salazopyrin			S				Pfizer	
	Chloroquine			S				Not Reported	
	Prednisone			C	Oral	5 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17139675	EXPEDITED (15-DAY)		HO, OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN- 002219			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>	
Acute Kidney Injury; Haemolysis; Jaundice; Pigment Nephropathy	Chloroquine Phosphate Artesunate			S C	Unknown Unknown	2.5 Gram Unk		Ipca Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2019	17139676	EXPEDITED (15-DAY)		HO, OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN- 002218			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>	
Acute Kidney Injury; Haemolysis; Jaundice; Pigment Nephropathy	Chloroquine Phosphate Artesunate			S C	Unknown Unknown	2.5 Gram Unk		Ipca Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2019	17139684	EXPEDITED (15-DAY)		HO, OT	IN-IPCA LABORATORIES LIMITED-IPC-2019-IN- 002217			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>	
Acute Kidney Injury; Haemolysis; Jaundice; Pigment Nephropathy	Chloroquine Phosphate Artesunate			S C	Unknown Unknown	2.5 Gram Unk		Ipca Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2019	16414474	EXPEDITED (15-DAY)		OT	PHHY2019PL132075		13 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>	
Steroid Diabetes	Ciclosporin			S	Unknown			Novartis	

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

Prednisone	S	Oral	Not Reported
Prednisone	S	Oral	Not Reported
Chloroquine	S	Unknown	Not Reported
Chloroquine	S	Unknown	Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	17154562	EXPEDITED (15-DAY)		OT	SE-CANTON LABORATORIES, LLC-2077835		68 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>	
Anxiety; Decreased Vibratory Sense; Dizziness; Drug Interaction; Erythema; Nerve Degeneration; Pain In Extremity; Peripheral Swelling; Polyneuropathy; Syncope; Systemic Lupus Erythematosus; Toxicity To Various Agents; Tremor	Naprosyn			S	Unknown			Canton Laboratories	
	Chloroquine			S	Unknown			Not Reported	
	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported	
	Indometacin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2019	16701250	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-216066		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acquired Pigmented Retinopathy; Maculopathy	Hydroxychloroquine			S	Unknown	Unk		Sun	
	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>
26-Dec-2019	15964245	EXPEDITED (15-DAY)		HO, OT	CO-ABBVIE-18K-036-2529937-00		64 YR	Male	COL

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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>	
Apnoea; Arthralgia; Arthritis; Blindness; Diaphragmatic Hernia; Drug Ineffective; Gastrointestinal Procedural Complication; Gastrooesophageal Reflux Disease; Hiatus Hernia; Laboratory Test Abnormal; Pain; Peritonitis; Rheumatoid Arthritis; Vision Blurred	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported	
	Prednisolone			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Loperamide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Dec-2019	15963285	EXPEDITED (15-DAY)		HO, LT, OT	NL-MYLANLABS- 2019M1012656		27 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>	
Cardiac Arrest; Circulatory Collapse; Electrocardiogram Qrs Complex Prolonged; Hypokalaemia; Intentional Overdose; Intentional Self- Injury; Pulseless Electrical Activity; Suicide Attempt; Toxic Encephalopathy	Flurazepam			S	Oral	Unk		Not Reported	
	Flurazepam			S		Unk		Not Reported	
	Chloroquine			S		Unk		Mylan	
	Clonidine			C		Unk		Mylan	
	Dextroamphetamine /00016601/			C		Unk		Mylan	
	Promethazine			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17219556	NON-EXPEDITED			US-PFIZER INC- 2019560663			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atenolol			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Clindamycin			S		Unk		Pfizer	
	Labetalol Hydrochloride			S		Unk		Unknown	

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Levofloxacin	S	Unk	Pfizer
Metoprolol Tartrate	S	Unk	Unknown
Augmentin [Amoxicillin Sodium;Clavulanate Potassium]	S	Unk	Not Reported
Botulinum Toxin	S	Unk	Not Reported
Chloroquine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17266958	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020013002			Female	CAN

<u>Preferred Term</u>	<u>Product</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	Methotrexate Sodium			S	Subcutaneous	25 Mg, Unk		Unknown
	Methotrexate Sodium			S	Oral	Unk		Pfizer
	Varenicline Tartrate			S	Unknown	Unk		Pfizer
	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer
	Azathioprine			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Mg, 2x/Day		Not Reported
	Asaphen			C	Unknown	80 Mg, Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Nasacort			C	Unknown	55 Ug, Unk		Not Reported
	Pantoprazole Magnesium			C	Unknown	40 Mg, 1x/Day		Not Reported
	Prednisone			C	Unknown	10 Mg, 1x/Day		Not Reported
	Synthroid			C	Unknown	220 Ug, 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>
16-Jan-2020	17275965	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-0398			Female	CAN

<u>Preferred Term</u>	<u>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; Diarrhoea; Hypersensitivity; Joint Swelling; Musculoskeletal Stiffness; Nausea; Pain; Rash; Retinal Toxicity; Vomiting	Methotrexate (Trade Name Unknown)	S	Oral	Not Reported
	Methotrexate (Trade Name Unknown)	S	Subcutaneous	Not Reported
	Varenicline Tartrate	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Azathioprine	S	Unknown	Not Reported
	Chloroquine	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Asaphen	C	Unknown	Not Reported
	Folic Acid	C	Unknown	Not Reported
	Nasacort	C	Unknown	Not Reported
	Pantoprazole Magnesium	C	Unknown	Not Reported
	Prednisone	C	Unknown	Not Reported
	Synthroid	C	Unknown	Not Reported
	Warfarin 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>
17-Jan-2020	17148770	EXPEDITED (15-DAY)		OT	CO-ABBVIE-19K-036- 3191331-00		57 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Cystitis; Furuncle; Pyrexia; Skin Disorder; Viral Infection; Weight Decreased	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Medrol			S	Oral			Not Reported
	Chloroquine			S	Oral			Not Reported
	Methotrexate			C	Subcutaneous			Not Reported
	Calcium			C	Oral			Not Reported
	Calcitriol			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	16350826	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL		69 YR	Unknown	ITA

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

INDUSTRIES LTD-
2019RR-208672

<u>Preferred Term</u>	<u>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		Astrazeneca
	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, Comprese Rivestite Con Film Timod			S	Oral	362.5 Milligram, Daily		Not Reported
				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>
23-Jan-2020	10298114	EXPEDITED (15-DAY)		DE, HO, OT	US-SA-2014SA047646		1 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product By Child; Accidental Overdose; Amylase Increased; Apnoea; Blood Alkaline Phosphatase Increased; Blood Creatinine Increased; Blood Potassium Increased; Blood Sodium Decreased; Blood Urea Increased;	Aralen			S	Oral	300 Mg,1x		Sanofi
	Acetylsalicylic Acid			C		Unk		Not Reported
	Acetylsalicylic Acid			C				Not Reported

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Body Temperature
Decreased; Bradycardia;
Brain Death; Brain
Herniation; Brain Oedema;
Electrocardiogram Qrs
Complex Prolonged;
Hyperglycaemia;
Hypotension; Pupillary
Light Reflex Tests
Abnormal; Pupils Unequal;
Seizure; Sinus
Tachycardia;
Unresponsive To Stimuli;
Urine Output 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>
28-Jan-2020	17335281	EXPEDITED (15-DAY)		OT	CA-SA-2020SA017636			Female	CAN

<u>Preferred Term</u>	<u>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	Leflunomide			S		20 Mg, Qd		Sanofi
	Methotrexate			S	Subcutaneous	25 Mg, Qw		Not Reported
	Chloroquine (Salt Not Specified)			S	Unknown	Unk		Sanofi
	Sulfasalazine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17338098	EXPEDITED (15-DAY)		OT	CA-SA-2020SA019284		63 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Primary Biliary Cholangitis; Psoriatic Arthropathy	Leflunomide			S	Unknown	Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	250 Mg		Sanofi
	Methotrexate			S	Unknown	Unk		Not Reported
	Enbrel			S	Subcutaneous	50 Mg, Qw		Not Reported
	Simponi			C		50 Mg, Qm		Not Reported
	Sulfasalazine			C		1 G, Bid		Not Reported

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	Xeljanz		C	Oral		5 Mg, Bid			Not Reported
	Xeljanz		C	Oral		5 Mg, Bid			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17342675	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2020M1010166		68 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>	
Decreased Vibratory Sense; Dizziness; Drug Interaction; Erythema; Nerve Degeneration; Pain In Extremity; Peripheral Swelling; Syncope; Toxicity To Various Agents	Indometacin			S		Unk		Not Reported	
	Indometacin			S		Unk		Not Reported	
	Ciprofloxacin			S		Unk		Not Reported	
	Chloroquine			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2020	16105902	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2019120790			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>	
Basedow'S Disease; Depression; Hypothyroidism; Obesity; Psoriasis	Methotrexate Sodium			S		25 Mg, Weekly		Pfizer	
	Salazopyrin			S		1 G, 2x/Day		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>
04-Feb-2020	15592728	EXPEDITED (15-DAY)		OT	ZA-SAKK-2018SA304134AA			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>	
Drug Ineffective; Osteoarthritis; Tuberculin Test Positive; White Blood Cell Count Decreased	Arava			S	Unknown			Sanofi	
	Methotrexate			S		Unk		Not Reported	
	Chloroquine Sulfate			S		Unk		Sanofi	
	Sulfasalazine			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17420980	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2020064178		32 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>
Alanine Aminotransferase Increased; Anxiety Disorder; C-Reactive Protein Increased; Drug Ineffective; Fibromyalgia; Joint Swelling; Loss Of Personal Independence In Daily Activities; Major Depression; Rheumatoid Arthritis; Sleep Apnoea Syndrome	Methotrexate			S		25 Mg, Unk		Pfizer
	Salazopyrin			S		2 G, Unk		Pfizer
	Chloroquine			S		200 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2020	17423522	EXPEDITED (15-DAY)		OT	CA-ROCHE-2549981			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Synovitis	Rituxan			S	Unknown	Solution Intravenous		Not Reported
	Humira			S	Subcutaneous	Solution Subcutaneous		Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Chloroquine			S	Unknown			Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Enbrel			C				Not Reported
	Methotrexate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2020	17424164	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1184277		31 YR	Female	CAN

<u>Preferred Term</u>	<u>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

Crying; Drug Ineffective; Joint Swelling	Leflunomide	S	Unknown		Barr
	Methotrexate	S	Unknown		Barr
	Chloroquine	S	Unknown		Not Reported
	Amitriptyline	C		150 Milligram Daily;	Not Reported
	Esomeprazole Magnesium Trihydrate/Naproxen	C			Not Reported
	Folate	C			Not Reported
	Pariet	C		40 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2020	15156214	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA183651			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>
Alopecia; Anxiety; Cachexia; Depression; Drug Intolerance; Job Dissatisfaction; Weight Decreased	Arava			S	Unknown	Unk		Sanofi
	Chloroquine (Salt Not Specified)			S	Unknown	200 Mg, Qd		Sanofi
	Methotrexate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2020	17413694	EXPEDITED (15-DAY)		OT	PHHY2019SE002330		68 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>
Anxiety; Decreased Vibratory Sense; Dizziness; Drug Interaction; Erythema; Nerve Degeneration; Neuropathy Peripheral; Pain In Extremity; Peripheral Swelling; Polyneuropathy; Syncope; Systemic Lupus Erythematosis; Toxicity To Various Agents; Tremor	Ciprofloxacin Hydrochloride			S	Unknown	500 Mg, Bid		Novartis
	Naproxen			S	Unknown	500 Mg, 2x/Day (Bid Was Continued)		Not Reported
	Indometacin			S	Unknown	Unk		Not Reported
	Chloroquine			S	Unknown	250 Mg, Daily (More Than Five Years)		Not Reported
	Chloroquine			S				Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439060	EXPEDITED (15-DAY)		OT	ZA-SA-2020SA036863		29 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>	
Arthropathy; Impaired Work Ability; Leukopenia; Nodule; Rheumatoid Arthritis	Chloroquine (Salt Not Specified)			S		200 Mg		Sanofi	
	Arava			S		20 Mg		Sanofi	
	Methotrexate Sodium			C		20 Mg		Not Reported	
	Arcoxia			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2020	17376191	EXPEDITED (15-DAY)		OT	NG-BAUSCH-BL-2020-003411		30 YR	Female	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dystonia	Metronidazole			S	Intravenous (not otherwise specified)	Seven-Day Course Post-Operatively		Not Reported	
	Metronidazole			S	Oral			Not Reported	
	Chloroquine Phosphate			S	Oral	Once, On The Sixth Day Post Operatively		Not Reported	
	Ampicillin			C	Oral	Postoperatively		Not Reported	
	Benylin			C		Before Chloroquine Administration		Not Reported	
	Acetaminophen			C		2 Tablets Prn		Not Reported	
	Folic Acid			C				Not Reported	
	Promethazine			C	Intramuscular			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Feb-2020	16231133	EXPEDITED (15-DAY)		OT	CA-SA-2019SA110410			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Drug	Hydroxychloroquine Sulfate			S		Unk Unk, Unk		Sanofi	
	Chloroquine (Salt Not Specified)			S	Oral	400 Mg, Qd		Sanofi	

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Ineffective; Drug	Methotrexate	S		25 Mg, Qw	Not Reported
Ineffective; Drug	Methotrexate	S	Oral	10 Mg, Qw	Not Reported
Ineffective; Juvenile	Humira	S	Subcutaneous	40 Mg	Not Reported
Idiopathic Arthritis; Polyarthritis	Prednisone	C	Oral	7 Mg, Qd	Not Reported
	Etanercept	C		50 Mg, Qw	Not Reported
	Cosentyx	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-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;	Methotrexate Sodium			S	Oral	25 Mg, Weekly		Pfizer
Impaired Work Ability;	Chloroquine			S		200 Mg, Daily		Not Reported
Rheumatoid Arthritis	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;	Salazopyrin En			S		1 G, 2x/Day		Pfizer
Osteoarthritis;	Nivaquine [Chloroquine]			S		200 Mg, Daily		Not Reported
Seronegative Arthritis	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	Intravenous (not otherwise specified)	Unk		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	16971400	NON-EXPEDITED		OT	ZA-AMGEN- ZAFSP2018039633		61 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>	
Malignant Melanoma; Off Label Use; Upper Respiratory Tract Infection	Enbrel			S	Unknown	25 Milligram, Every 2 Weeks		Amgen	
	Abitrexate			S	Subcutaneous	15 Milligram, Unk		Not Reported	
	Plasmoquine			S	Unknown	200 Milligram 3/Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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 Ineffective; Drug Intolerance; Fatigue; Red Blood Cell Sedimentation Rate Increased; Rheumatoid Factor Positive; Synovitis; Treatment Failure	Neoral			S	Subcutaneous			Novartis	
	Neoral			S	Oral	Unk		Novartis	
	Leflunomide			S	Unknown			Not Reported	
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported	
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported	
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported	
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported	
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported	
	Methotrexate Sodium			S	Subcutaneous	20 Mg		Not Reported	
	Methotrexate Sodium			S	Oral	20 Mg		Not Reported	
	Cyclosporine			S	Unknown			Novartis	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Chloroquine			S	Subcutaneous			Not Reported	
	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg		Not Reported	

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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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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 Aggravated; Diverticulitis; H1n1 Influenza; Hepatic Enzyme Increased; Hepatomegaly; Palpitations; Pneumonia; Renal Disorder; Tooth	Methotrexate			S	Unknown			Barr	
	Chloroquine Diphosphate			S	Unknown			Not Reported	
	Belimumab			S	Unknown			Not Reported	
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported	

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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
<u>Preferred Term</u>	<u>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;	Remicade			S	Intravenous (not otherwise specified)	Last Infusion: 04-Mar-2020		Not Reported	
Incorrect Drug	Remicade			S				Not Reported	
Administration Rate;	Chloroquine			S	Unknown			Not Reported	
Infusion Related Reaction;								Not Reported	
Insomnia; Mucous Stools;								Not Reported	
Off Label Use; Pain;								Not Reported	
Systemic Lupus								Not Reported	
Erythematousus								Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	Methotrexate Sodium			S		30 Mg, Weekly		Pfizer	
Hyperplasia; Prostate	Arava			S		20 Mg, Daily		Not Reported	
Cancer	Chloroquine			S	Oral	200 Mg, Daily		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
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	
	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	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	

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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 Erythematous Rash; Tremor; Underdose; Vaginal Haemorrhage; Weight Decreased; Weight Increased	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 Issue; Joint Swelling; Off Label Use; Pain;	Methotrexate			S	Unknown			Not Reported
Pulmonary Embolism; Pulmonary Thrombosis;	Methotrexate			S				Not Reported
Red Blood Cell Sedimentation Rate Increased; Renal Failure; Sepsis; Thrombosis	Actemra			S	Unknown			Not Reported
	Actemra			S				Not Reported
	Anakinra			S	Unknown			Not Reported
	Anakinra			S				Not Reported
	Arava			S	Unknown			Not Reported
	Arava			S				Not Reported
	Enbrel			S	Unknown			Not Reported
	Enbrel			S				Not Reported
	Humira			S	Subcutaneous	Solution		Not Reported
	Humira			S				Not Reported
	Chloroquine Phosphate			S	Unknown			Not Reported

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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>
31-Mar-2020	15208555	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2017517635		57 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>	
Back Pain; Post Procedural Complication	Enbrel			S	Subcutaneous	25 Mg, 2x/Week		Pfizer	
	Methotrexate			S		25 Mg, Unk		Pfizer	
	Plasmoquine			S		1 Week		Not Reported	

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

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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	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/MI Vial, Sq			C				Not Reported	
	As Directed							Not Reported	

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

Neupogen 300 Mcg/ 0.5ml Syringe, Sq	C	Not Reported
Venofer 200 Mg/10ml Vial Iv As Directed	C	Not Reported
Chloroquine Ph 250 Mg, Daily	C	Not Reported
Chloroquine Ph 250 Mg, Daily	C	Not Reported
Venofer 200mg /10ml Vial Iv	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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>
Arthralgia; Arthritis; Bronchitis; Death; Decreased Appetite; Dry Eye; Dysphagia; Gait Disturbance; Glossodynia; Hypoaesthesia; Inappropriate Schedule Of Product Administration; Joint Swelling; Lip Erythema; Oral Discomfort; Oropharyngeal Pain; Osteoarthritis; Pain In Extremity; Peripheral Coldness; Pneumonia; Product Dose Omission; Renal Disorder;	Benlysta			S		550 Mg, Unk		Glaxosmithkline
	Benlysta			S		500 Mg		Glaxosmithkline
	Chloroquine Phosphate			S		250 Mg, Unk		Glaxosmithkline
	Paracetamol			C		Unk		Glaxosmithkline
	Crestor			C		Unk		Glaxosmithkline
	Colecalciferol			C		Unk		Glaxosmithkline
	Methotrexate			C		Unk		Glaxosmithkline
	Mycophenolate			C		Unk		Glaxosmithkline
	Calcium			C		Unk		Glaxosmithkline
	Glucosamine			C		Unk		Glaxosmithkline
	Clopidogrel			C		Unk		Glaxosmithkline
						Unk		Glaxosmithkline

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Therapeutic Product Effect	Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Decreased; Tongue Erythema; Underdose;	Prednisone	C		5 Mg, Unk	Not Reported
Urinary Tract Infection; Visual Impairment; Weight	Chondroitin	C		Unk	Not Reported
Decreased; Weight Fluctuation; Wrong	Amytril	C		Unk	Not Reported
Product Administered; Wrong Technique In	Rivotril	C		Unk	Not Reported
Product Usage Process	Endofolin	C		Unk	Not Reported
	Alginac	C		Unk(1000)	Not Reported
	Cilostazol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-			Unknown	FRA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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; Polyarthritits; Skin Lesion; Treatment Failure; Uveitis	Humira			S	Unknown			Not Reported
	Leflunomide			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Aralen			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Sodium Aurothiomalate			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	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;	Arava			S		10 Mg, Qw		Sanofi
	Sulfasalazine			S		1 G, Bid		Not Reported

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

Seronegative Arthritis	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
	Dormonoc	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Apr-2020	15230238	NON-EXPEDITED		OT	ZA-AMGEN-ZAFSP2017181416		57 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>
Back Pain; Post Procedural Complication	Enbrel			S	Subcutaneous	25 Milligram, 2x/Week		Amgen
	Methotrexate			S	Unknown	25 Milligram, Unk		Not Reported
	Plasmoquine			S	Unknown	1 Week		Not Reported

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

FDA Adverse Event Reporting System

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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	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;	Methotrexate Sodium			S		Unk		Pfizer
	Remicade			S		Unk		Not Reported
	Aralen Hydrochloride			S		Unk		Not Reported

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

Skin Lesion; Uveitis	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

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	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	
	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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-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>
Anxiety; Choking; Circumstance Or Information Capable Of Leading To Medication Error; Cough; Decreased Appetite; Depressed Mood; Depression; Dyspnoea; Emotional Distress; Eye Disorder; Fatigue; Fear; Haematoma; Hypotension; Inappropriate Schedule Of Product Administration; Limb Injury; Malaise; Memory Impairment; Nasopharyngitis; Nephrolithiasis; Nervousness; Pain In Extremity; Poor Quality Sleep; Product Availability Issue; Product Dose Omission; Retinal	Benlysta			S		960 Mg, Unk		Glaxosmithkline
	Chloroquine Phosphate			S		Unk		Glaxosmithkline
	Cortisone Acetate			C		Unk		Glaxosmithkline
	Seretide			C		Unk		Glaxosmithkline
	Velija			C		Unk (60)		Not Reported
	Deflazacort			C		6 Mg, Bid		Not Reported
	Alprazolam			C		Unk		Not Reported

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

Disorder; Skin
Discolouration; Stress;
Systemic Lupus
Erythematosis;
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>
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
	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

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

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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>
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

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Musculoskeletal Stiffness; Polyarthritis; Skin Lesion; Uveitis	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	17688868	EXPEDITED (15-DAY)		OT	CA-SA-2020SA100832			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deformity; Movement Disorder; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S				Sanofi	
	Methotrexate			S				Not Reported	
	Leflunomide			S		Unk		Sanofi	
	Chloroquine Sulfate			S				Sanofi	
	Myochrysine			S				Not Reported	
	Humira			S				Not Reported	
	Remicade			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	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; Polyarthritis; Skin Lesion; Treatment Failure; Uveitis	Plaquenil			S	Unknown			Sanofi	
	Aralen			S	Unknown			Sanofi	
	Leflunomide			S	Unknown			Sanofi	
	Methotrexate			S	Unknown			Not Reported	
	Sodium Aurothiomalate			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	

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Remicade			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
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	

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Folkodin Alkaloid	C	Not Reported
Lekadol C	C	Not Reported
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 Disorder; Lip Disorder;	Leflunomide			S	Unknown			Not Reported
Pigmentation Disorder;	Trimethoprim/Sulfamethoxazole			S	Unknown			Not Reported
Skin Lesion; Skin Lesion;	Chloroquine			S	Unknown			Not Reported
Stevens-Johnson Syndrome; Toxic	Prednisone			S	Unknown			Not Reported
Epidermal Necrolysis;	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
Toxic Epidermal Necrolysis; Toxic	Prednisolone			S	Nasal			Not Reported
Epidermal Necrolysis								

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Nivaquine			S	Oral	200 Milligram, Once A Day (2-3 Cp Per Day)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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 Prolonged; Off Label Use;	Resochin 250 Mg			S	Oral	0.5 G, Bid		Bayer
Product Use In Unapproved Indication	Resochin 250 Mg			S				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>
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
	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>
27-Apr-2020	17672253	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200411530		49 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Contraindicated Product Administered; Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Seronegative	Simponi			S	Subcutaneous			Janssen
	Simponi			S				Janssen
	Cosentyx			S	Unknown			Not Reported

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Arthritis; Treatment Failure	Enbrel	S	Unknown	Not Reported
	Hydroxychloroquine	S	Unknown	Not Reported
	Hydroxychloroquine	S		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Celebrex	S	Unknown	Not Reported
	Chloroquine Diphosphate	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Orencia	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Erythromycin	C	Unknown	Not Reported
	Morphine	C	Topical	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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>
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Off Label Use; Pneumonitis; Product Use In Unapproved Indication	Actemra	S	Intravenous (not otherwise specified)	Not Reported
	Tamiflu	S	Oral	Not Reported
	Chloroquine	S	Oral	Not Reported
	Azithromycin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17721471	EXPEDITED (15-DAY)	LT		FR-TEVA-2020-FR-1227414		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Nivaquine [Chloroquine Sulfate]			S	Oral	2-3 Cp Per Day:200 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
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	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
	Azitromicina			S				Not Reported
	Tamiflu			S				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
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 Chloroquine			S S				Not Reported Not Reported	