

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	AZITHROMYCIN			
Active Moiety:				
FDA Received Date:	From:	01-Mar-2020	To:	01-Oct-2020
MedDRA® Version* :	23.0			
Total Cases**:	306			
Number of Pages:	154			

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.

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17-Mar-2020	14334309	EXPEDITED (15-DAY)		OT	ES-GLAXOSMITHKLINE-ES2017197792			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>	
Apnoea; Deafness; Off Label Use; Tonsillitis	Flixotide			S	Unknown	Unk		Glaxosmithkline	
	Zitromax			S	Unknown	1 MI, From Monday To Thursday On, From Friday To Sunday Off		Not Reported	
	Zitromax			S	Unknown	1.5 MI, From Monday To Thursday On, From Friday To Sunday Off		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17566575	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020119949		11 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysentery	Zitromax			S	Oral	10 MI, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569863	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1206667		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Toxic	Azitromicina (7019a)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577149	EXPEDITED (15-DAY)		OT	NVSC2020CA082846		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>	
Pneumonia; Vaginal Infection; Vulvovaginal Pruritus	Sandoz Azithromycin			S	Unknown	250.0 Mg, Unknown		Novartis	
	Clotrimazole			S	Unknown	Unk Unk, Unknown		Not Reported	

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	Desoximetasone		S	Unknown		Unk Unk, Unknown			Not Reported
	Stelara		S	Intravenous (not otherwise specified)		Unk Unk, Q2mo			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17590223	DIRECT		OT			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Balance Disorder; Dizziness; Nausea; Suspected Product Contamination; Vomiting	Azithromycin Tablet Usp, 250 Mg			S	Oral	Quantity:1 Capsule(S);		Teva Pharmaceuticals Industries	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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	17604086	DIRECT					29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Chest Discomfort; Chest Pain; Dizziness; Palpitations; Tachycardia	Azithromycin 250mg Tablets 6- Pak			S	Oral	Quantity:2 Tablet(S);		Sandoz	
	D Amphetamine Salt Combo 10mg			C				Not Reported	
	Albuteral Hfa Inh 8I5mg			C				Not Reported	
	Magnesium Oxide 250mg			C				Not Reported	
	Melatonin 1mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083- 3348747-00		57 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax			S	Oral			Not Reported	

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03-Apr-2020	17620205	EXPEDITED (15-DAY)		HO, OT	IT-GLAXOSMITHKLINE-IT2020057146		57 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Chills; Nausea; Rash	Valaciclovir Hydrochloride			S	Oral	Unk		Glaxosmithkline	
Pruritic; Syncope; Vomiting	Zitromax			S	Oral	Unk		Glaxosmithkline	
	Tachidol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17639031	NON-EXPEDITED			US-SLATE RUN PHARMACEUTICALS-SLTR-AE-20-10		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Ascites; Dyspnoea; Ejection Fraction Decreased; Hepatic Enzyme Increased; Hepatomegaly; International Normalised Ratio Increased; Left Ventricular Failure; Mental Impairment; Oedema Peripheral	Enteric-Coated Aspirin			C				Not Reported	
	Digoxin			C				Not Reported	
	Donepezil			C				Not Reported	
	Memantine			C				Not Reported	
	Fluoxetine			C				Not Reported	
	Latanoprost			C				Not Reported	
	Metformin			C				Not Reported	
	Glipizide			C				Not Reported	
	Rivaroxaban			C				Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported	
	Hydrocodone			C	Oral			Not Reported	
	Acetaminophen			C	Oral			Not Reported	
	Cholecalciferol			C				Not Reported	
	Piperacillin-Tazobactam			C	Intravenous (not otherwise specified)	4.5g Iv Loading Dose		Not Reported	
	Vancomycin			C	Intravenous (not otherwise specified)	3000 Mg Iv Loading Dose		Not Reported	
	Furosemide			C	Intravenous (not otherwise specified)			Not Reported	
	70436-019-82 Azithromycin For			S	Intravenous (not			Hainan Poly	

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Injection Dry Vial Usq 500 Mg

otherwise specified)

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>
09-Apr-2020	17652024	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020142626		57 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Chills; Nausea; Rash Pruritic; Syncope; Vomiting	Zitromax			S	Oral	Unk		Pfizer	
	Tachidol			S	Oral	Unk		Not Reported	
	Zelitrex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661808	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1035752		52 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Dysgeusia; Haematochezia; Vomiting	Azithromycine Mylan 200 Mg/5 Ml, Poeder Voor Orale Suspensie			S	Oral	1 Dosage Form, Qd(1x Per Day One Bottle)		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	17664526	DIRECT	Y	HO, LT			81 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>	
Anaphylactic Reaction; Pharyngeal Swelling; Respiratory Distress; Stridor	Azithromycin (Azithromycin 250mg Tab)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sudden Death	Levofloxacin (2791a)			S	Unknown			Teva	

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	Hidroxiclороquina Sulfato (2143su)	S	Oral	200 Mg	Teva
	Azitromicina (7019a)	S	Oral	500 Mg	Not Reported
	Lopinavir+Ritonavir	S	Oral	4 Dosage Forms Daily;	Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous	40 Mg	Not Reported
	Prednisona (886a)	C	Oral	20 Mg	Not Reported
	Ceftriaxona (501a)	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670568	EXPEDITED (15-DAY)		HO	NVSC2020ES099621		26 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azitromicina Sandoz			S	Oral	500 Mg Dia		Novartis
	Ibuprofeno Sandoz			S	Oral	1-1-1-1		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500mg/24h		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679380	EXPEDITED (15-DAY)		HO, LT	NL-TEVA-2020-NL-1223674		55 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>
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Hepatic Enzyme Abnormal; Thrombocytopenia	Azithromycine	S	500 Milligram Daily; 1 Piece Once A Day	Not Reported
	Azithromycine	S		Not Reported
	Loperamide	C	Capsule, 2 Mg (Milligram)	Not Reported
	Prednisolon	C	Capsule, 15 Mg (Milligram)	Not Reported
	Novorapid (Insuline Aspart)	C	Injection Liquid, 100 Units / MI (Units Per Milliliter)	Not Reported
	Furosemide	C	40 Mg (Milligram)	Not Reported

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17-Apr-2020	17680902	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224376		46 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg Day		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 400 Mg Day		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17687783	DIRECT	Y	HO			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myasthenia Gravis Crisis	Azithromycin (Azithromycin 250mg Cap)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683592	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-002338		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Eye Irritation; Lacrimation Increased	Azithromycin 250 Mg Tablets	S	Unknown	Unk	Aurobindo
	Usp				
	Lisinopril	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>
20-Apr-2020	17683593	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-007051		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Azithromycin 250 Mg Tablets Usp			S	Unknown	2 Tablets For First Day And 1 Tablet For Next Four Days		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683594	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-007417			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Feeling Abnormal; Malaise	Azithromycin 250 Mg Tablets Usp			S	Unknown	Unk		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>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	17518555	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-010869			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Gastrointestinal Pain; Malaise; Product Physical Issue; Product Substitution Issue; Rectal Haemorrhage; Toxicity To Various Agents	Azithromycin 250 Mg Tablets Usp			S	Oral	2 Dosage Form, Daily, 1 In The Morning And 1 In The Evening		Aurobindo	
	Azithromycin 250 Mg Tablets Usp			S				Aurobindo	
	Cipro			S	Unknown	Unk		Not Reported	
	Doxycycline			C	Unknown	Unk		Not Reported	
	Doxycycline			C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689685	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226003		66 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Amoxicilina / Clavulanico (Amoxicillin/Clavulanic Acid)			S	Oral	875 Mg,1 Df		Teva	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>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	17690548	EXPEDITED (15-DAY)		OT	CN-BAXTER-2020BAX008147		86 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Dysgeusia; Hypoaesthesia Oral; Nausea; Pallor	Metronidazole And Sodium Chloride Injection			S	Intravenous drip			Baxter	
	Fuqixing			S	Intravenous drip			Not Reported	
	Sodium Chloride			S	Intravenous drip	Sodium Chloride Injection + Fuqixing Injection		Not Reported	
	Pantoprazole Sodium			S	Intravenous drip			Not Reported	
	Pantoprazole Sodium			S	Intravenous drip			Not Reported	
	Glucose			S	Intravenous drip			Not Reported	
	Sodium Chloride			S	Intravenous drip	Sodium Chloride Injection + Pantoprazole Sodium Injection		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690794	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226002		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hepatitis	Azitromicina (7019a)	S	Oral	500 Milligram Daily; 500 Mg/24h	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Hidroxiclороquina (2143a)	S	Oral	200 Milligram Daily; 200 Mg/24h	Teva
	Hidroxiclороquina (2143a)	S			Teva
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Milligram Daily; 600mg/24h	Not Reported
	Tocilizumab (8289a)	S			Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h	Not Reported
	Ceftriaxona (501a)	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691425	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225669		33 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400mg		Teva
	Hidroxiclороquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Does 500 Mg		Not Reported
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Dose 250 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h, Unit Dose 2 Gm		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17694029	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225643		68 YR	Male	ESP

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg		Teva	
	Hidroxicloroquina (2143a)			S	Oral	1er Día 400 Mg/12 H, A Partir Del 2º Día 400mg/24 H		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg 1st Dose, Later 250mg / 24h		Not Reported	
	Azitromicina (7019a)			S	Oral			Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; Single Dose		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	17697469	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226211		63 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Daily		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17662214	EXPEDITED (15-DAY)		OT	CH-EMD SERONO-E2B_90076477		37 YR	Female	CHE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Premenstrual Syndrome	Gonal-F			S	Subcutaneous	In Total		Not Reported	
	Gonal-F			S				Not Reported	
	Cetrotide			S		Therapy Start Date: Jan 2019		Serono	
	Puregon /01348901/			S		Therapy Start Date: Jan 2019		Not Reported	
	Orgalutran			S	Subcutaneous	In Total		Not Reported	

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Decapeptyl /00975902/	S	Subcutaneous	In Total	Not Reported
Decapeptyl /00975902/	S	Subcutaneous	In Total	Not Reported
Azithromycine	S		In Total	Not Reported
Ethinylestradiol/Levonorgestrel	S		Therapy Start Date: Jan 2019 Ethinylestradiol: 0.02 Mg And Levonorgestrel: 0.1 Mg	Not Reported
Menopur	S		Therapy Start Date: Jan 2019	Not Reported
Merional	S		Therapy Start Date: Jan 2019	Not Reported
Trazodone	C			Not Reported
Trazodone	C			Not Reported
Zoloft	C			Not Reported
Dalmadorm	C			Not Reported
Imovane	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17702988	EXPEDITED (15-DAY)	HO		ES-TEVA-2020-ES-1226290		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Milligram Daily; Route Of Administration: Sng		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703265	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226288		65 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiogenic Shock; Drug Interaction;	Hidroxiclороquina Sulfato (2143su)			S	Oral	200 Mg		Teva
Tachyarrhythmia	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported

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Tocilizumab (8289a)	C	Intravenous (not otherwise specified)		Not Reported
Ceftriaxona (501a)	C	Intravenous (not otherwise specified)	1 Gram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703479	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3376441-00		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705944	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226289		28 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1 Gram Every 8 Hours		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17702991	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226210		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction; Propofol Infusion Syndrome	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Propofol 2% Injectable Baxter, 1	S	Intravenous (not otherwise specified)	Sedation	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported
	Dexametasona (722a)	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>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	17709497	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1226643		20 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>	
Stevens-Johnson Syndrome	Azitromicina (7019a)			S	Oral	500 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-Apr-2020	17709947	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226986		63 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;			Not Reported
	Azitromicina (7019a)			S					Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S					Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily;			Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; Every 8 Hours			Not Reported
	Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec			S					Not Reported

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27-Apr-2020	17710025	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226989		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710046	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226987		36 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 120 Tablets		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 30 Tablets		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712080	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226652		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500		Not Reported	

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		Azitromicina (7019a)	S		Mg/24h				
		Hidroxycicloroquina (2143a)	S	Oral	400 Milligram Daily; 400 Mg/24h				Not Reported Teva
		Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600mg Single Dose				Not Reported
		Tocilizumab (8289a)	S						Not Reported
		Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h				Not Reported
		Ceftriaxona (501a)	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712129	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226773		49 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxycicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712393	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226967		65 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712394	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226772		30 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715790	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226775		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17678663	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224966		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Dolquine 200 Mg Compridos Recubiertos, 30 Compridos			S	Oral	Unit Dose : 200 Mg 400mg Day		Not Reported	

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		Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos Ceftriaxona (501a)		S					Not Reported
				S	Intravenous (not otherwise specified)	2 Gr Day			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17691116	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1225788		62 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hepatitis; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715976	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-017172		1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error; Product Reconstitution Quality Issue	Azithromycin For Oral Suspension Usp 200 Mg/5ml			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721734	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227334		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg, 1			S	Intravenous (not otherwise specified)	C/24 H		Not Reported	
	Ertapenem (2881a)			S	Intravenous (not	1 Gram Daily;		Not Reported	

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		otherwise specified)	
Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;
Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722337	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227335		50 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725765	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC-20200432974		72 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Durogesic Matrix			S	Transdermal	Patch 25 Mcg/H : 1 Tous Les 3 Jours		Janssen	
	Plaquenil /00072602/			S	Oral	800 Mg/Jour Du 22 Au 23.03.2020, 400 Mg/Jour Du 24 Au 26.03.2020, 600 Mg/Jour Du 26 Au 30.03.2020		Not Reported	
	Doxycycline			S	Oral			Not Reported	
	Azithromycine			S	Oral			Not Reported	

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		Amoxicillin And Clavulanate		S		Intravenous drip			Not Reported
		Potassium		S		Subcutaneous			Not Reported
		Enoxaparin		S					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17727439	DIRECT	Y	DE			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction; Cardiac Arrest; Cardiogenic Shock; Renal Failure	Hydroxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral				Not Reported
	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)	Other Strength:500 Mg/Vil;			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727996	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000002			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown				Hainan Poly Pharmaceutical
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17721946	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227338		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;			Not Reported
	Azitromicina (7019a)			S					Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;			Not Reported
	Ceftriaxona (501a)			S					Not Reported
	Dolquine			S	Oral	400 Milligram Daily; Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			Not Reported

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Dolquine			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17740193	DIRECT		HO			29 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Hypertension; Skin Discolouration; Swollen Tongue; Tachycardia	Azitrocin	Y		S	Intramuscular	Quantity:4 Df Dosage Form;	2 DAY	Pfizer	
	Collagen			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736837	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1228515		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741986	EXPEDITED (15-DAY)		CA, OT	US-SLATE RUN PHARMACEUTICALS-20US000026			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>	
Ammonia Increased; Asthma; Blood Lactic Acid Increased; Cognitive Disorder; Communication Disorder; Congenital Nose Malformation; Developmental Delay; Disturbance In Social Behaviour; Ear Infection;	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	

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Fall; Febrile Convulsion;
General Physical
Condition Abnormal;
Hypotonia; Insulin-Like
Growth Factor Decreased;
Jaundice Neonatal;
Microcephaly;
Micrognathia; Seizure;
Sensory Processing
Disorder; Sleep Apnoea
Syndrome; Speech
Disorder Developmental;
Stereotypy; Weight Gain
Poor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17745843	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI-1228870		68 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Sumamed 500 Mg			S	Intravenous (not otherwise specified)	200 Mg		Not Reported	
	Hydroxychloroquine Sulfate 200 Mg			S	Oral	200 Mg, The First Day 1000mg, Then 500mg, Therapy Lasted For 3 Days		Teva	
	Midazolam			C				Not Reported	
	Lopinavir/Ritonavir			C				Not Reported	
	Paracetamol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2020	17746335	EXPEDITED (15-DAY)		DE	US-SLATE RUN PHARMACEUTICALS-20US000055			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Off Label Use	Azithromycin Usp			S	Intravenous (not otherwise specified)	Unk		Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	

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Hydroxychloroquine	S	Unknown	Unk, Single	Not Reported
Methotrexate	C	Unknown		Not Reported
Steroids	C		Unk	Not Reported
Steroids	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750116	EXPEDITED (15-DAY)		DE, HO	ES-TEVA-2020-ES-1230679		70 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Bundle Branch Block Right; Hypertension; Hypofibrinogenaemia; Pneumonia Escherichia; Ventricular Tachycardia	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17750118	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230310		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754170	EXPEDITED (15-DAY)		DE	ES-BAUSCH-BL-2020-012998		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Electrocardiogram Qt Prolonged; Sudden Death	Salbutamol (2297a)	S	Respiratory (inhalation)		Bausch And Lomb
	Dolquine	S	Oral	30 Tablets	Not Reported
	Metoclopramida (1958a)	S	Intravenous (not otherwise specified)		Not Reported
	Propofol (2373a)	S	Intravenous (not otherwise specified)		Not Reported
	Azitromicina (7019a)	S	Oral		Not Reported
	Ipratropio Bromuro (1067br)	C	Respiratory (inhalation)		Not Reported
	Cefotaxima (3840a)	C	Intravenous drip		Not Reported
	Midazolam (2256a)	C	Intravenous drip		Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous		Not Reported
	Tocilizumab (8289a)	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2020	17754512	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230680		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Paracetamol (12a)			S	Intravenous (not otherwise specified)	1gr Every 8 Hours		Not Reported	
	Metamizol (111a)			S	Intravenous (not otherwise specified)	2gr Every 6 Hours		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17715901	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1228878		39 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Mg		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg, Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported
	Propofol (2373a)			S	Intravenous (not otherwise specified)			Not Reported
	Metoclopramida (1958a)			S	Intravenous (not otherwise specified)	10 Mg, Metoclopramida (1958a)		Not Reported
	Ipratropio Bromuro (1067br)			C	Respiratory (inhalation)	20 Mcg		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous			Not Reported
	Cefotaxima (3840a)			C	Intravenous drip	4gram		Not Reported
	Midazolam (2256a)			C	Intravenous drip	100 Mg		Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17754993	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1230791		47 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Paracetamol (12a)			S	Oral	3 Gram Daily;		Not Reported
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	75 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755116	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1230945		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Day		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500mg Day		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17755361	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1231568		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400mg Daily		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500mg Daily		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Anakinra (2699a)			S	Subcutaneous	100 Mg		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Daily		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757730	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395337-00		68 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminaemia;	Kaletra			S	Oral			Not Reported	

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Off Label Use	Zitromax Avium	S	Oral	Not Reported
	Plaquenil	S	Oral	Not Reported
	Roactemra	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757800	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3395439-00		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2020	17757860	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3395468-00		70 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763349	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232236		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763369	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1232936		58 YR	Male	ESP

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Pancreatitis Acute	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Metilprednisolona (888a)			S	Intravenous (not otherwise specified)	250 Mg		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	560 Mg		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	200 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763509	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1232933		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported	
	Propofol			S	Unknown			Not Reported	
	Propofol			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos			S	Oral	A Compressed Breakfast And Dinner 200 Milligram		Not Reported	
	Midazolam (2256a)			S	Unknown			Not Reported	
	Midazolam (2256a)			S				Not Reported	
	Kaletra			S	Oral			Not Reported	
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported	
	Manidon Hta 240 Mg Comprimidos De Liberacion Prolongada, 30 Comprimido			C				Not Reported	
	Rilast Turbuhaler 160 Microgramos/4,5 Microgramos/Inhalacion Polvo Pa			C				Not Reported	
	Omnice Ocas 0,4 Mg			C				Not Reported	

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Comprimidos De Liberacion Prolongada Recubiertos Con Simvastatina 20 Mg 28 Comprimidos	C				Not Reported
Kalpress 160 Mg Comprimidos Recubiertos Con Pelicula, 28 Comprimidos (Cortic - Corticoide	C				Not Reported
	C	Unknown	Low Dose Corticoids		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763517	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232553		57 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763552	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1232937		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Loss Anaemia; Gastrointestinal Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	120 Milligram Daily; Unit Dose: 60 Mg		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Tocilizumab (8289a)			S				Not Reported

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Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Mg Day For 6 Days Followed By 10 Mg Day X 5 Days			Not Reported	
Dexametasona (722a)			S						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763555	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232242		79 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;			Not Reported
	Azitromicina (7019a)			S					Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;			Teva
	Hidroxicloroquina (2143a)			S					Teva
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763557	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232550		64 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;			Not Reported
	Azitromicina (7019a)			S					Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;			Teva
	Hidroxicloroquina (2143a)			S					Teva
	Levofloxacino (2791a)			S	Oral	500 Milligram Daily;			Teva
	Roactemra 20 Mg/ML, Concentrado Para Solucion Para Perfusion			S	Intravenous (not otherwise specified)	600 Mg			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2020	17763558	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1232237		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;			Not Reported
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;			Teva

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Hidroxicloroquina (2143a)			S				Teva		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17764415	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-01989		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Constipation; Diarrhoea; Dizziness; Dyspnoea; Fatigue; Feeling Abnormal; Headache; Hyperventilation; Pain	Azithromycin Tablets, 250 Mg			S	Oral	250 Milligram, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2020	17766323	DIRECT	Y				62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Rash; Urticaria	Azithromycin (Azithromycin 250mg Tab)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17770367	DIRECT	Y	HO, OT			80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tachyarrhythmia	Hydroxychloroquine			S	Oral			Not Reported	
	Azithromycin 500mg Daily			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2020	17771827	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC- 2020185943		76 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Erythema;	Norvasc			S	Oral	10 Mg, 1x/Day		Pfizer	
	Norvasc			S		Unk (Reduced Dose)		Pfizer	

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Rash Pustular	Ritonavir	S	Oral	100 Mg, 1x/Day	Not Reported
	Clexane T	S	Subcutaneous	6000 Kiu, 1x/Day	Not Reported
	Darunavir	S	Oral	800 Mg, 1x/Day	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	400 Mg, 1x/Day	Not Reported
	Azithromycin Teva	S	Oral	500 Mg, 1x/Day	Not Reported
	Eutirox	C		Unk	Not Reported
	Folifill	C		Unk	Not Reported
	Ceftriaxone	C	Oral	1 Df, 1x/Day	Not Reported
	Lasix [Furosemide]	C		Unk	Not Reported
	Urbason Solub	C	Intravenous (not otherwise specified)	1 Df, 1x/Day	Not Reported
	Omeprazole	C		Unk	Not Reported
	Trelegy Ellipta	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774466	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1233693		56 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Hypoacusis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17774467	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233697		57 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Roactemra			S	Intravenous (not			Not Reported

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					otherwise specified)				
		Roactemra		S					Not Reported
		Lopinavir/Ritonavir		S	Oral	4 Dosage Forms Daily;			Not Reported
		Lopinavir/Ritonavir		S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778628	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1233508		45 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg			Not Reported
	Azitromicina (7019a)			S					Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Mg			Teva
	Hidroxiclороquina (2143a)			S					Teva
	Doxiciclina (1395a)			S	Oral	100 Mg			Not Reported
	Doxiciclina (1395a)			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2020	17778629	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233662		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Hidroxiclороquina (2143a)			S	Oral	400 Mg			Teva
	Hidroxiclороquina (2143a)			S					Teva
	Azitromicina (7019a)			S	Oral	500 Mg			Not Reported
	Roactemra			C	Intravenous (not otherwise specified)	600 Mg			Not Reported
	Roactemra			C					Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	2 Gram			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	16889663	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019425004		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Off Label Use; Product Use In Unapproved Indication; Tachycardia		Zitromax	S	Oral	500 Mg, Single			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17780193	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233665		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Mg		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Enoxaparina (2482a)			S	Subcutaneous	40 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784210	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234252		72 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17784740	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234253		49 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	

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		Hidroxicloroquina (2143a)	S	Oral	400 Milligram Daily;		Teva		
		Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported		
		Ceftriaxona (501a)	S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785260	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234538		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785276	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234791		45 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234786		71 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported	

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Tocilizumab (8289a)			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17785505	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1234790		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Roactemra			S				Not Reported	
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787004	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020189427		64 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholangiolitis; Hypertransaminasaemia; Off Label Use	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	200 Mg, 1x/Day		Not Reported	
	Urbason Solub			C	Intravenous (not otherwise specified)	40 Mg		Not Reported	
	Antra [Omeprazole]			C		Unk		Not Reported	
	Clexane			C	Subcutaneous	4000 Kiu		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2020	17787014	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235520		83 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Condition Aggravated; Hyponatraemia	Azitromicina (7019a)	S	Oral	500 Mg Day	Not Reported
	Hidroxiclороquina (2143a)	S	Oral	400 Mg Day	Teva
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram	Not Reported
	Symbicort Turbuhaler 160 Microgramos/4,5	S	Respiratory (inhalation)	6 Dosage Forms Daily; 2- 2-2	Not Reported
	Microgramos/Inhalacion Polvo Salbutamol	S	Respiratory (inhalation)	6 Dosage Forms Daily; 2- 2-2 Inh	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17788439	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2020185645		365 DAY	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>	
Depressed Level Of Consciousness; Wrong Dose	Zitromax			S	Oral	400 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792157	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1234794		59 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Mg Day		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 G, Day		Not Reported	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2020	17792663	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1233509		35 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hepatitis	Hidroxiclороquina (2143a)	S	Oral	400 Mg Day	Teva
	Azitromicina (7019a)	S	Oral	500 Mg Day	Not Reported
	Rapamune	C	Oral	1 Mg	Not Reported
	Rapamune	C			Not Reported
	Enoxaparina (2482a)	C	Subcutaneous	40 Mg Day	Not Reported
	Deflazacort (2546a)	C	Oral	6 Mg	Not Reported
	Deflazacort (2546a)	C			Not Reported
	Deflazacort (2546a)	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794272	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234955		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg Day		Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Day		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2020	17794307	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1234956		71 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Day		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Mg Day		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported

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Tocilizumab (8289a)			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17798156	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1228873		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799012	EXPEDITED (15-DAY)			US-SLATE RUN PHARMACEUTICALS-20US000088			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>	
Therapy Non-Responder	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2020	17799090	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1235781		62 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Hypocoagulable State; Hypofibrinogenaemia; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Mg		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram Daily;		Not Reported	

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Enoxaparina (2482a)			S		otherwise specified) Subcutaneous		80 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-May-2020	17799108	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1235526		48 YR	Female	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported		
	Azitromicina (7019a)			S				Not Reported		
	Hidroxicloroquina (2143a)			S	Oral	400 Milligram Daily;		Teva		
	Hidroxicloroquina (2143a)			S				Teva		
	Colchicina (142a)			S	Oral	1 U Breakfast		Not Reported		
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported		
	Tocilizumab (8289a)			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-May-2020	17673548	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017887		74 YR	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Death	Levofloxacin Arrow Film-Coated Tablets 500mg			S	Oral	2 Dosage Form, Once A Day		Aurobindo		
	Sandoz Amoxi Clav			S	Oral	3 Dosage Form, Once A Day		Not Reported		
	Lovenox			S	Subcutaneous	1 Dosage Form, Once A Day		Not Reported		
	Primperan			S	Oral	1 Dosage Form		Not Reported		
	Ritonavir Mylan			S	Oral	1 Dosage Form, Once A Day		Not Reported		
	Azithromycin Sandoz [Azithromycin]			S	Oral	4 Dosage Form, Once A Day		Not Reported		
	Doliprane			S	Oral	1 Dosage Form		Not Reported		

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Plaquenil	S	Oral	3 Dosage Form, Once A Day	Not Reported
Darunavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17684775	EXPEDITED (15-DAY)		OT	IE-TEVA-2020-IE-1223586			Male	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Condition Aggravated; Depressed Mood; Drug Interaction; Frustration Tolerance Decreased; Gastrointestinal Disorder; Gastrointestinal Pain; Gastrointestinal Tract Irritation; Irritable Bowel Syndrome	Azithromycin Teva			S	Oral	Prescribed Dose = Two 250 Mg Tablets Daily For Three Days Taken Dose = 3 Tablets Taken Before Discon		Not Reported	
	Azithromycin Teva			S				Not Reported	
	Mag365 Exotic Lemon Flavour - Ionic Magnesium Citrate			S	Oral	1-2 Teaspoons Of It Daily, Mag365 Exotic Lemon Flavour - Ionic Magnesium Citrate		Not Reported	
	Penicillin (Benzylpenicillin Sodium)			S	Oral	Penicillin (Generic)		Not Reported	
	Pro-Ven [Dietary Supplement\Probiotics]			S	Oral	2 Sachets		Not Reported	
	Probiotics (Generic) Ireland			C				Not Reported	
	Probiotics (Generic) Ireland			C		2 Sachets		Not Reported	
	Turmeric			C	Oral	Additional Information : Substance Name : Curcuma Longa ,		Not Reported	
	Lithium Carbonate			C	Oral	100 Mg Taken Orally At Night Ongoing Dose Tapering - Original Dose Was 800mg Of Lithium Per Night, 1		Not Reported	
	Cod Liver Oil (G)			C	Oral	Daily		Not Reported	

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

Germentin 250mg/125mg Film-Coated Tablets

C

Oral

3 Tablets 3 Times A Day
For 7 Days

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2020	17805077	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020198909		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Azithromycine			S	Oral	500 Mg, 1x/Day		Pfizer
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2020	17806646	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1237680		67 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Rash Pruritic	Levofloxacin (2791a)			S	Intravenous (not otherwise specified)	500 Mg		Teva
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812272	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1049231		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>
Gamma-Glutamyltransferase Increased; Hepatocellular Injury; Off Label Use	Lopinavir/Ritonavir Mylan			S	Oral	4 Dosage Form		Mylan
	Cefotaxime Mylan			S	Intravenous (not otherwise specified)	3 Gram		Mylan
	Linezolid Kabi			S	Intravenous drip	1200 Milligram		Mylan

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Linezolid	S	Oral	1200 Milligram	Mylan
Azithromycine Sandoz /00944301/	S	Oral	250 Milligram	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17812551	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2020198926		66 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycine			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported
	Irbesartan Eg			S	Oral	Unk		Not Reported
	Carvedilol Arrow			S	Oral	Unk		Not Reported
	Lasilix			S	Oral	Unk		Not Reported
	Risordan			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2020	17813329	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES- 1236090		26 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	20 Milligram Daily;		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)			Not Reported
	Tocilizumab (8289a)			S				Not Reported
	Dexketoprofeno (7312a)			S	Intravenous (not otherwise specified)	75 Milligram Daily;		Not Reported
								Not Reported

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Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2020	17816728	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020202244		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Off Label Use; Product Use Issue	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
	Inhixa			C	Subcutaneous	40 Mg		Not Reported	
	Sirtap			C	Intravenous (not otherwise specified)	2 G		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2020	17818807	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3414053-00		77 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821010	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020200438		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycine Pfizer			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821038	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020204019		41 YR	Male	ITA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminasaemia; Off Label Use; Product Use In Unapproved Indication	Zitromax Avium			S	Oral	1 Df, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	2 Df, 1x/Day		Not Reported	
	Kaletra			S	Oral	4 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821532	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000130			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Bradycardia; Cardiomyopathy; Electrocardiogram Qt Prolonged; Hypothermia; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported	
	Propofol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821576	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000132			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2020	17821661	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000133			Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17396633	NON-EXPEDITED			PHHY2019US194994		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Skin Discolouration; Weight Decreased	Lamprene			S	Oral	100 Mg, Qd		Novartis	
	Lamprene			S	Oral	100 Mg, Qod		Novartis	
	Azithro			S	Unknown	Unk Unk, Qod		Not Reported	
	Etham (Ethambutol Dihydrochloride)			S	Unknown	Unk Unk, Qod		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822635	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083-3418091-00		58 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral	Zitromax Avium 600 Mg Comprese Rivest		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17822923	EXPEDITED (15-DAY)		HO	IT-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020-12-02		84 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Cholestasis; Hepatic	Pradaxa	S	Oral	Boehringer Ingelheim
Enzyme Increased; Liver	Trajenta	S	Oral	Boehringer Ingelheim
Injury	Zitromax	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2020	17823842	EXPEDITED (15-DAY)		HO	US-SLATE RUN PHARMACEUTICALS- 20US000136			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;	Azithromycin Usp			S	Unknown	Unk		Hainan Poly
Eosinophilia; Haematuria;	Tacrolimus			C	Unknown	Unk		Pharmaceutical
Transplant Rejection;								Not Reported
Tubulointerstitial Nephritis								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2020	17829680	EXPEDITED (15-DAY)		OT	BR-PFIZER INC- 2020204768		60 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
Electrocardiogram Qt								
Prolonged; Off Label Use;	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
Product Use In	Reuquinol			S	Oral	400 Mg, Daily ((Given In 2 Divided Doses Every 12 Hours)		Not Reported
Unapproved Indication	Reuquinol			S		400 Mg, Daily (Given In 2 Divided Doses Every 12 Hours)		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, 2x/Day		Not Reported
	Oseltamivir			C	Oral	75 Mg, 2x/Day		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day (Every 8 Hours)		Not Reported
	Tazocin			C	Intravenous (not otherwise specified)	4.5 G, 4x/Day (Every 6hours)		Not Reported

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

Vancomycin Hydrochloride	C	Intravenous (not otherwise specified)	1 G, 2x/Day (Every 12hours)	Not Reported
Vancomycin Hydrochloride	C	Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported
Dobutamine	C		Unk	Not Reported
Sodium Bicarbonate	C		Unk	Not Reported
Cis [Cisatracurium Besilate]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	40 Mg	Not Reported
Sodium Chloride	C		Unk	Not Reported
Dopacris	C	Intravenous (not otherwise specified)	250 Mg, As Needed	Not Reported
Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Nexium Mups [Esomeprazole Magnesium]	C		20 Mg, 1x/Day	Not Reported
Lipless	C		Unk	Not Reported
Hydrochlorothiazide	C		Unk	Not Reported
Trezor [Rosuvastatin Calcium]	C		Unk	Not Reported
Metformin	C		Unk	Not Reported
Losartan	C		Unk	Not Reported
Tamiram	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2020	17835073	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204798		65 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Fibrin D Dimer	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer

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Increased; Gastrointestinal Haemorrhage; Haematochezia; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication; Product Use Issue	Reuquinol	S	Oral	400 Mg, 2x/Day	Not Reported
	Reuquinol	S	Oral	400 Mg, 1x/Day	Not Reported
	Oseltamivir [Oseltamivir Phosphate]	C		Unk Unk, 2x/Day	Not Reported
	Ceftriaxone	C		Unk	Not Reported
	Bromoprida	C	Intravenous (not otherwise specified)	10 Mg, 3x/Day	Not Reported
	Clexane	C	Subcutaneous	80 Mg, 2x/Day	Not Reported
	Amiodarone Hcl	C	Intravenous (not otherwise specified)	900 Mg, As Needed	Not Reported
	Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
	Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Ug, As Needed	Not Reported
	Noradrenaline [Norepinephrine]	C	Intravenous (not otherwise specified)	16 Mg, As Needed	Not Reported
	Lactulona	C	Oropharyngeal	20 MI, 3x/Day	Not Reported
	Lasix [Furosemide]	C	Intravenous (not otherwise specified)	20 Mg, As Needed	Not Reported
	Luftal Max	C	Oropharyngeal	40 Drop, 3x/Day	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Oropharyngeal	20 Mg, 1x/Day	Not Reported
	Nujol	C	Oropharyngeal	20 MI, 3x/Day	Not Reported
	Zinforo	C	Intravenous (not otherwise specified)	600 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17763565	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1231867		76 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Erythema; Off Label Use; Rash Pustular	Azitromicina Teva Italia (Azithromycin)			S	Oral	500 Mg		Not Reported	
	Darunavir			S	Oral	800 Mg		Teva	

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Ritonavir Sandoz	S	Oral	100 Mg	Not Reported
Norvasc 5 Mg Compresse	S	Oral	10 Mg	Not Reported
Clexane T	S	Subcutaneous	6000 Ku	Not Reported
Plaquenil	S	Oral	400 Mg	Not Reported
Eutirox	C			Not Reported
Folifill	C			Not Reported
Ceftriaxone Mylan Generics 2000 Mg Polvere Per Soluzione Per Infusione	C	Oral	1 Df	Not Reported
Lasix Fiale	C			Not Reported
Urbason Solubile	C	Intravenous (not otherwise specified)	1 Df	Not Reported
Omeprazole	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17825815	EXPEDITED (15-DAY)		OT	BR-PFIZER INC- 2020204791		72 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Pyrexia	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Reuquinol			S	Oral	400 Mg, 1x/Day		Not Reported
	Ceftriaxona [Ceftriaxone]			C	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Clexane			C	Subcutaneous	40 Mg, 1x/Day		Not Reported
	Euthyrox			C	Oral	37.5 Mg, 1x/Day		Not Reported
	Lorazepam			C	Oral	2 Mg, 1x/Day		Not Reported
	Nexium [Esomeprazole Magnesium]			C	Oral	20 Mg, 2x/Day (Every 12 Hours)		Not Reported
	Novalgina			C	Intravenous (not otherwise specified)	1 G, Every 6 Hours As Needed		Not Reported
	Meclin			C	Oral	50 Mg, 2x/Day		Not Reported
	Puran T4			C		37.5 Ug, 1x/Day		Not Reported
	Domperidone			C		10 Mg, 1x/Day		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17825820	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2020204785		62 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Electrocardiogram Qt Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication; Pyrexia	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Reuquinol			S	Oral	400 Mg, 2x/Day 12/12h		Not Reported	
	Reuquinol			S		400 Mg, 1x/Day		Not Reported	
	Reuquinol			S		200 Mg, 1x/Day		Not Reported	
	Atorvastatin Calcium			C		10 Mg, 1x/Day		Not Reported	
	Oseltamivir			C	Oral	75 Mg, 2x/Day		Not Reported	
	Zinforo			C	Intravenous (not otherwise specified)	600 Mg, 2x/Day		Not Reported	
	Zinforo			C	Intravenous (not otherwise specified)	400 Mg, 2x/Day		Not Reported	
	Zinforo			C	Intravenous (not otherwise specified)	600 Mg, 2x/Day		Not Reported	
	Merone			C	Intravenous (not otherwise specified)	1 G, 3x/Day 8 / 8h		Not Reported	
	Linezolid			C	Intravenous (not otherwise specified)	600 Mg, 2x/Day		Not Reported	
	Sodium Bicarbonate			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Bromoprida			C	Intravenous (not otherwise specified)	10 Mg, 3x/Day		Not Reported	
	Potassium Chloride			C		Unk		Not Reported	
	Sodium Chloride			C		Unk		Not Reported	
	Dormire [Midazolam Hydrochloride]			C	Intravenous (not otherwise specified)	100 Mg, As Needed (As Physician Criteria)		Not Reported	
	Fentanest [Fentanyl Citrate]			C	Intravenous (not otherwise specified)	2500 Ug, As Needed (As Physician Criteria)		Not Reported	
	Hemofol			C	Subcutaneous	5000 Iu, 3x/Day		Not Reported	

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Hepamax S	C	Unk	Not Reported
Nexium [Esomeprazole Magnesium]	C	20 Mg, 1x/Day	Not Reported
Aradois	C	50 Mg, 1x/Day	Not Reported
Somalgin	C	81 Mg, 1x/Day	Not Reported
Exodus [Escitalopram Oxalate]	C	10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17830178	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1239952		40 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Hypertransaminasaemia	Hidroxiclороquina (2143a)			S	Oral	400 Mg W / 12 Hours Followed By 200 Mg W / 12 Hours. 1 Dosage Forms		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Unknown	Not Specified		Not Reported
	Ceftriaxona (501a)			S	Unknown	Not Specified		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprímodos Recubiertos Con P			S	Oral	400 Mg C / 12 Drops.2 Dosage Forms		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprímodos Recubiertos Con P			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2020	17841275	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2020-ES-1240532		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Thrombocytopenia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Roactemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Enoxaparina (2482a)			S	Subcutaneous	160 Milligram Daily;		Not Reported

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31-May-2020	15646436	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-056188		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azithromycin 500 Mg Film-Coated Tablets			S	Oral	500 Milligram, Daily, Azitro/24h 6d		Aurobindo	
	Capoten			C	Oral	25 Milligram, Two Times A Day		Not Reported	
	Adiro			C	Oral	300 Milligram, Daily		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
	Ibuprofen			C	Oral	Unk, Has Been Taking 1-2cp Daily In The Last 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-Jun-2020	17835217	EXPEDITED (15-DAY)		DS	FR-PFIZER INC-2020205714		54 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Peripheral Sensory Neuropathy; Product Use In Unapproved Indication	Cresemba			S	Oral	2 Df, 1x/Day		Unknown	
	Azithromycine			S	Oral	750 Mg, Weekly		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846438	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1241766		57 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Piperacilina Tazobactam			S	Intravenous (not otherwise specified)	1 Amp/8h		Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram Daily;		Not Reported	

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otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2020	17846772	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241463		56 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Aziticomicina (7019a)			S	Oral	500 Milligram		Not Reported Teva	
	Hidroxicloroquina 200 Mg Comprimido			S		200 Milligram			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2020	17850433	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1241768		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	400 Mg Day		Teva Not Reported Not Reported Not Reported	
	Aziticomicina (7019a)			S		500 Mg Day			
	Enoxaparina (2482a)			S		60 Mg			
	Roactemra			S		Intravenous (not otherwise specified)	600 Mg		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2020	17858935	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020204764		64 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Protein C Decreased; Protein C Increased	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer Pfizer Not Reported Not Reported Not Reported	
	Azithromycin			S		500 Mg, 1x/Day			
	Quinacris			S		500 Mg, 2x/Day			
	Kaletra			S		2 Df, 2x/Day			
	Bromoprida			C		Intravenous (not otherwise specified)	30 Mg, 3x/Day		

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	Vancomicina [Vancomycin Hydrochloride]	C	Intravenous (not otherwise specified)	1 G, 2x/Day	Not Reported
	Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
	Euthyrox	C	Other	50 Ug, 1x/Day	Not Reported
	Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Mg, As Needed	Not Reported
	Norepinefrina [Norepinephrine Bitartrate]	C	Intravenous (not otherwise specified)	16 Mg, As Needed	Not Reported
	Ionclor	C	Other	20 Ml, 3x/Day	Not Reported
	Lasix [Furosemide]	C	Intravenous (not otherwise specified)	30 Mg, 3x/Day	Not Reported
	Meronom	C	Intravenous (not otherwise specified)	1 G, 3x/Day	Not Reported
	Muvinalax	C	Oral	14 G, 2x/Day	Not Reported
	Nexium [Esomeprazole Magnesium]	C	Oral	20 Mg, 1x/Day	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, 2x/Day	Not Reported
	Hydroxychloroquine	C	Other	400 Mg, 2x/Day	Not Reported
	Simvastatin	C		10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2020	17776859	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1233507		27 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis; Rash	Azitromicina (7019a)			S	Oral	250 Milligram Daily;		Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Nordimet 22,5 Mg Solucion Inyectable En Pluma Precargada, 4 Plumas Pre			C	Subcutaneous	1 Iny Sc On Monday		Not Reported
	Isdiben 20 Mg Capsulas Blandas , 50 Cápsulas			C	Oral	1 Cp Every 48 Hours, 20 Mg		Not Reported

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08-Jun-2020	17871321	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245871		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Mg Every 12 Hours Followed By 200 Mg Every 12 Hours		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Unknown	2 Gram		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Hbpm - Heparina De Bajo Peso Molecular (Hbpm) (Sin Especificar)			C				Not Reported	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			C	Oral	400 Mg Every 12 Hours, 1 Dosage Form		Not Reported	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			C				Not Reported	
	Sintrom			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17676221	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223885		43 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not	2 Doses In Total, 2		Not Reported	

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Tocilizumab (8289a)			S		otherwise specified)		Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Jun-2020	17873763	EXPEDITED (15-DAY)		OT	CA-APOTEX-2020AP011525		65 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Pain Lower; Aphonia; Cough; Intentional Product Use Issue; Vomiting	Acetaminophen			S	Unknown	Unk		Apotex		
	Gd Azithromycin			S	Unknown	250 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>	
09-Jun-2020	17873997	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245815		35 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hypertriglyceridaemia	Azitromicina (7019a)			S	Oral			Not Reported		
	Hidroxiclороquina Sulfato (2143su)			S	Oral			Teva		
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported		
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Jun-2020	17874172	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245927		66 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Atrial Fibrillation	Hidroxiclороquina Sulfato (2143su)			S	Oral			Teva		
	Azitromicina (7019a)			S	Oral			Not Reported		
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported		

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Kaletra 200 /50 Mg Comprimidos
Recubiertos Con Pelicula, 120
Comprimid

S

Oral

2 Dosage Forms

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17874658	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245817		72 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypertriglyceridaemia; Rhabdomyolysis	Azitromicina (7019a)			S	Oral			Not Reported
	Hidroxiclороquina Sulfato (2143su)			S	Oral			Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875624	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245925		50 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>
Hypertriglyceridaemia	Hidroxiclороquina Sulfato (2143su)			S	Oral			Teva
	Azithromycin (7019a)			S	Oral			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosageform		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17875785	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1245924		33 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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Hypertriglyceridaemia; Liver Disorder	Hidroxiclороquina Sulfato (2143su)	S	Oral	Teva
	Azitromicina (7019a)	S	Oral	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	Not Reported
	Kaletra 200 /50 Mg Comprimid Recubiertos Con Pelicula, 120 Comprimid	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17876460	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000182			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Off Label Use	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Prenatal Vitamins [Minerals Nos; Vitamins Nos]			C	Unknown	Unk		Not Reported	
	Aspirin [Acetylsalicylic Acid]			C	Unknown	Unk		Not Reported	
	I.V. Solutions			C	Intravenous (not otherwise specified)			Not Reported	
	Ceftriaxone			C	Unknown			Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Betamethasone			C	Unknown			Not Reported	
	Oxygen			C	Unknown			Not Reported	
	Norepinephrine			C	Unknown	6 Microgram /Min		Not Reported	
	Norepinephrine			C	Unknown	30 Microgram /Min		Not Reported	
	Norepinephrine			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17877035	EXPEDITED (15-DAY)		HO, OT	US-SLATE RUN PHARMACEUTICALS- 20US000183			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Apgar Score Low; Premature Baby; Pulmonary Haemorrhage Neonatal	Azithromycin Usp	S	Transplacental	Hainan Poly Pharmaceutical Not Reported
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]	C	Transplacental	
	Aspirin [Acetylsalicylic Acid]	C	Transplacental	Not Reported
	Ceftriaxone	C	Transplacental	Not Reported
	I.V. Solutions	C	Transplacental	Not Reported
	Hydroxychloroquine	C	Transplacental	Not Reported
	Betamethasone	C	Transplacental	Not Reported
	Oxygen	C	Transplacental	Not Reported
	Norepinephrine	C	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2020	17877288	EXPEDITED (15-DAY)		HO, OT	US-SLATE RUN PHARMACEUTICALS- 20US000184			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>	
Apgar Score Low; Premature Baby; Sars- Cov-2 Test Positive	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical Not Reported	
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]			C	Transplacental			Not Reported	
	Aspirin [Acetylsalicylic Acid]			C	Transplacental			Not Reported	
	Ceftriaxone			C	Transplacental			Not Reported	
	I.V. Solutions			C	Transplacental			Not Reported	
	Hydroxychloroquine			C	Transplacental			Not Reported	
	Betamethasone			C	Transplacental			Not Reported	
	Oxygen			C	Transplacental			Not Reported	
	Norepinephrine			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	14309917	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2017535884			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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Apnoea; Deafness; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Tonsillitis	Zitromax	S	1 MI, From Monday To Thursday On, From Friday To Sunday Off	Pfizer
	Zitromax	S	1.5 MI, From Monday To Thursday On, From Friday To Sunday Off	Pfizer
	Flixotide	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>
10-Jun-2020	17865550	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2020218356		77 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zitromax			S				Pfizer	
	Amiodarone			S	Intravenous (not otherwise specified)	600 Mg, Loading Dose		Not Reported	
	Amiodarone			S		900 Mg, Daily		Not Reported	
	Amiodarone			S	Oral	200 Mg, 2x/Day		Not Reported	
	Domperidone			S		10 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>
10-Jun-2020	17878489	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246782		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>	
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown			Not Reported	
	Kaletra 200 /50 Mg Compridos Recubiertos Con Pelicula, 120 Comprimid			S	Oral			Not Reported	
	Dolquine 200 Mg Compridos Recubiertos, 30 Compridos			S	Oral	400 Mg		Not Reported	
	Ceftriaxona (501a)			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-Jun-2020	17880134	EXPEDITED (15-DAY)		DS, HO	NVSC2020CH155813		62 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Peripheral Artery Thrombosis; Peripheral Ischaemia	Torasemid Sandoz 2,5 Mg Tablett			S	Oral	2.5 Mg, Qd		Not Reported
	Azithromycin Sandoz 500, Filmtabletten			S	Oral	500 Mg, Qd		Novartis
	Actemra			S	Intravenous (not otherwise specified)	800 Mg, Qd		Not Reported
	Plaquenil			S	Oral	400 Mg, Bid		Not Reported
	Plaquenil			S	Oral	200 Mg, Bid		Not Reported
	Amlodipin Pfizer			C	Oral	10 Mg, Qd		Not Reported
	Valsartan Sandoz			C	Oral	160 Mg, Bid		Not Reported
	Remeron			C	Sublingual	7.5 Mg, Qd		Not Reported
	Co-Amoxi			C	Oral	625 Mg, Q8h		Not Reported
	Clarithromycin Sandoz			C	Oral	500 Mg, Q12h		Not Reported
	Fragmin			C	Subcutaneous	5000 Iu, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17880974	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246149		59 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Azitromicina (7019a)			S	Oral			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral			Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral			Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882152	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000177			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Off Label Use	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Clindamycin			S	Unknown	Unk		Not Reported	
	Quinine			S	Unknown			Not Reported	
	Atovaquone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2020	17882293	EXPEDITED (15-DAY)		HO	US-SLATE RUN PHARMACEUTICALS- 20US000178			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 Myeloid Leukaemia; Extramedullary Haemopoiesis; Off Label Use	Azithromycin Usp			S	Unknown	5 Milligram Per Kilogram, Qd		Hainan Poly Pharmaceutical	
	Azithromycin Usp			S	Unknown	10 Milligram Per Kilogram, Single		Hainan Poly Pharmaceutical	
	Azithromycin Usp			S	Transplacental	Unk		Hainan Poly Pharmaceutical	
	Clindamycin			S	Transplacental			Not Reported	
	Quinine			S	Transplacental			Not Reported	
	Atovaquone			S	Unknown	20 Milligram Per Kilogram, Q 12 Hr		Not Reported	
	Atovaquone			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>
11-Jun-2020	17884746	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES- 1246778		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Hepatitis Cholestatic	Hidroxiclороquina Sulfato (2143su)	S	Oral	400 Mg	Teva
	Azitromicina (7019a)	S	Oral	500 Mg	Not Reported
	Kaletra 200 /50 Mg Compridos Recubiertos Con Pelicula, 120 Comprimid	S	Oral	2 Dosage Forms	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Interferon Beta-1a (2305ou)	S	Subcutaneous	30 Microgram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2020	17885849	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246780		78 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown			Not Reported
	Kaletra 200 /50 Mg Compridos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	Unit Dose: 4 Dosage Forms		Not Reported
	Ceftriaxona (501a)			S	Unknown			Not Reported
	Dolquine 200 Mg Compridos Recubiertos, 30 Compridos			S	Oral	Unit Dose: 400 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2020	17887405	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1246783		71 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Unknown			Not Reported
	Dolquine 200 Mg Compridos Recubiertos, 30 Compridos			S	Oral	400 Mg		Not Reported
	Kaletra 200 /50 Mg Compridos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	4 Dosage Form		Not Reported
	Ceftriaxona (501a)			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>
12-Jun-2020	17889956	EXPEDITED (15-DAY)		HO	NVSC2020ES162469		57 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Subarachnoid Haemorrhage	Atorvastatin			S	Oral	10 Mg, Qd (0-0-1 10 Mg Comprimidos)		Novartis	
	Enalapril			S	Oral	30 Mg, Qd (20 Mg 0 - 10 Mg)		Not Reported	
	Allopurinol			S	Oral	100 Mg, Qd (100 Mg Dia)		Not Reported	
	Azibect			S	Oral	10 Mg, Qd (0-0-1 10 Mg Comprimidos Efg, 28 Comprimidos)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17894108	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1247509		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Hypertransaminaemia	Hidroxiclороquina (2143a)			S				Teva	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S	Oral	2 Dosage Forms Daily; 400 Mg Every 12 Hours		Not Reported	
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P			S				Not Reported	
	Bufomix Easyhaler 320 Microgramos/9 Microgramos/Inhalacion Polvo Para			C				Not Reported	
	Paracetamol (12a)			C				Not Reported	
	Condrosan 400 Mg Capsulas Duras			C				Not Reported	
	Vesicare 5 Mg Comprimidos			C				Not Reported	

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Recubiertos Con Pelicula		
Prednisona (886a)	C	Not Reported
Alprazolam 2 Mg Comprimido	C	Not Reported
Axiago 20 Mg Comprimidos	C	Not Reported
Gastrorresistentes		
Atorvastatina 20 Mg Comprimido	C	Not Reported
Lyrica 150 Mg Capsulas Duras	C	Not Reported
Clexane	C	Not Reported
Lorazepam 5 Mg Comprimido	C	Not Reported
Sintrom 4 Mg Comprimidos	C	Not Reported
Movalis 15 Mg Capsulas	C	Not Reported
Doclis Retard 120 Mg Capsulas	C	Not Reported
Duras De Liberacion Prolongada		
Rivotril 2 Mg Comprimidos	C	Not Reported
Montelukast 10 Mg Comprimido	C	Not Reported
Optovite B12 1.000 Microgramos	C	Not Reported
Solución Inyectable		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17900086	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1247758		60 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hyperbilirubinaemia; Long Qt Syndrome	Hidroxiclороquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Hidroxiclороquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Hidroxiclороquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S		500 Mg		Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	1 Dosage Form		Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	1 Dosage Form		Not Reported
	Atorvastatina [Atorvastatin]			C	Oral	20 Mg		Not Reported
	Telmisartan And Hydrochlorothiazide Tablets (80 Mg/25 Mg), Usp			C	Oral	80 Mg		Not Reported
	Metformina 850 Mg 50 Comprimidos			C	Oral	850 Mg		Not Reported

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Tocilizumab			C		600 Mg			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17902397	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1455824		52 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Rhabdomyolysis	Hidroxicloroquina Sulfato (2143su)			S	Oral			Teva	
	Azitromicina (7019a)			S	Oral			Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)			Not Reported	
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2020	17906782	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS-20US000213			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Torsade De Pointes	Azithromycin Usp			S	Intravenous (not otherwise specified)	500 Milligram		Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S	Unknown	400 Gram, Bid		Not Reported	
	Plasma			C	Intravenous (not otherwise specified)	1 Dosage Form (1 Unit)		Not Reported	
	Rocephin [Ceftriaxone Sodium]			C	Intravenous (not otherwise specified)	2 Gram, Qd		Not Reported	
	Heparin			C	Unknown			Not Reported	
	Ephedrine			C	Intravenous (not otherwise specified)	Unk, Prn		Not Reported	
	Hydrocortisone			C	Intravenous (not otherwise specified)	Unk, Prn		Not Reported	
	Remdesivir			C	Intravenous (not	100 Milligram, Qd		Not Reported	

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Remdesivir			C		otherwise specified) Intravenous (not otherwise specified)		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>	
17-Jun-2020	17907754	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1787871		29 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)				S	Oral	400 Milligram Daily;		Teva	
	Azitromicina (7019a)				S	Intravenous (not otherwise specified)	500 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-Jun-2020	17813252	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020198921		71 YR	Male	ITA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Feeling Hot; Flushing; Senile Pruritus; Skin Exfoliation; Skin Reaction	Zitromax				S	Oral	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]				S	Oral	400 Mg, 1x/Day		Not Reported	
	Rezolsta				C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2020	17909820	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES-1788338		50 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>	
Atrial Fibrillation; Mixed Liver Injury	Azitromicina (7019a)				S	Oral	500 Mg		Not Reported	
	Hidroxiclороquina Sulfato (2143su)				S	Oral	400 Mg		Teva	
	Ceftriaxona (501a)				S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Kaletra 200 /50 Mg Comprimid Recubiertos Con Pelicula, 120 Comprimid				S	Oral	2 Dosage Forms		Not Reported	

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Interferon Beta-1b (23050d)

S

Subcutaneous

30 Microgram

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	17910914	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1788047		63 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort	Aziticromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	200 Mg		Teva
	Amoxicilina/Acido Clavulanico 1.000 Mg/200 Mg Inyectable			S	Intravenous (not otherwise specified)	1 Dosage Form		Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	2 Dosage Forms		Not Reported
	Atrovent 20 Microgramos Solucion Para Inhalacion En Envase A Presion, Acido Folico 5 Mg 28 Comprimidos			C	Respiratory (inhalation)	40 Mcg		Not Reported
	Trimbow 87 Microgramos/5 Microgramos/9 Microgramos Solucion Para Inhal			C	Respiratory (inhalation)	2 Dosage Forms		Not Reported
				C	Oral	5 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17913474	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1788337		50 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>
Diarrhoea; Hepatitis; Hypertriglyceridaemia	Hidroxiclороquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Aziticromicina (7019a)			S	Oral	500 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2020	17914776	EXPEDITED (15-DAY)		OT	NVSC2020NL095683			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>	
Diarrhoea; Diarrhoea Haemorrhagic; Gastric Hypermotility; Product Taste Abnormal; Product Use In Unapproved Indication; Vomiting	Azithromycin 200 Mg/5 ML, Poeder Voor Orale Suspensie			S	Oral	1 Df, Qd (1 Bottle)		Novartis	
	Azithromycin/Teva			C	Oral	1 Df, Qd (1 Bottle)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jun-2020	17883536	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES- 1246786		79 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Interferon Beta-1b (2305od)			S	Subcutaneous	30 Mg		Not Reported	
	Ivemend 150 Mg Polvo Para Solucion Para Perfusion, 1 Vial			S	Oral	2 Dosage Forms		Not Reported	
	Cefotaxima (3840a)			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17914440	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES- 1788339		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>	
Atrial Fibrillation	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Hidroxiclороquina Sulfato (2143su)			S	Oral	400 Mg		Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported	
	Rezolsta 800 Mg / 150 Mg Comprimidos Recubiertos Con Película 30 Compr			S	Oral	1 Dosage Forms		Not Reported	

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

Kaletra 200 /50 Mg Compridos
Recubiertos Con Pelicula, 120
Comprimid

C

Oral

2 Dosage Forms

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2020	17915612	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1788678		69 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>
Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported
	Kaletra 200 /50 Mg Compridos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported
	Interferon Beta-1b (2305od)			S	Subcutaneous	30 Microgram		Not Reported
	Cefotaxima (3840a)			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>
20-Jun-2020	16205710	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-019697		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Dyspnoea; Malaise; Peripheral Swelling; Pneumonia; Throat Irritation	Amlodipine Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Amlodipine Tablets			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Valsartan			S	Unknown	160 Milligram, Once A Day		Aurobindo
	Apo-Amlodipine			S	Unknown	10 Milligram, Once A Day		Not Reported
	Xolair			S	Subcutaneous	375.0 Milligram, 1 Every Two Week		Not Reported
	Azithro			S	Unknown	25 Milligram		Not Reported
	Budesonide			C	Unknown	4.0 Dosage Form, Daily		Not Reported
	Claritin			C	Unknown	1.0 Dosage Form, Daily		Not Reported
	Spiriva			C	Unknown	1 Dosage Form, Once A		Not Reported

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Alvesco	C	Unknown	Day	Not Reported
Symbicort	C	Unknown	2 Dosage Form, Two Times A Day	Not Reported
			4 Dosage Form, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17924254	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1788903		59 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Long Qt Syndrome	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Lopinavir+Ritonavir			S	Oral			Not Reported
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)	800 Mg		Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2020	17925821	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1789183		69 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>
Hyperbilirubinaemia	Hidroxicloroquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Interferon Beta-1a (2305ou)			S	Subcutaneous	30 Mcg		Not Reported
	Kaletra 200 /50 Mg Comprimid			S	Oral	200/50 Mg, 2 Df		Not Reported
	Levofloxacin (2791a)			S	Intravenous (not otherwise specified)	500 Mg		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>
22-Jun-2020	17925877	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000219			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Off Label Use	Azithromycin Usp			S	Intravenous (not otherwise specified)			Hainan Poly Pharmaceutical	
	Prenatal Vitamins [Minerals Nos; Vitamins Nos] Oxygen			C	Unknown	Unk, Qd		Not Reported	
	Ceftriaxone			C	Nasal			Not Reported	
				C	Intravenous (not otherwise specified)			Not Reported	
	Metoprolol			C	Oral	12.5 Milligram, Bid (After Delivery)		Not Reported	
	Metoprolol			C	Oral	12.5 Milligram, Bid (Before Delivery)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17907407	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1787868		52 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	400mg Every 12 Hours Followed By 200mg Every 12 Hours, Unit Dose: 1 Df Hidroxiclороquina (2143a)		Teva	
	Hydroxychloroquine Sulfate Accord Lopinavir W/Ritonavir			S	Oral	2 Df Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con Pelicula Efg , 120 Comprim		Not Reported	
	Accord Lopinavir W/Ritonavir			S				Not Reported	

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

	Ceftriaxona (501a)		S	Intravenous (not otherwise specified)	2 G			Not Reported	
	Ceftriaxona (501a)		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17929306	EXPEDITED (15-DAY)		OT	NVSC2020FR173175		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycine Sandoz 250 Mg Filmomhulde Tabletten			S	Oral	500 Mg(J1, Puis 250 Mg/Jour)		Novartis	
	Azithromycine Sandoz 250 Mg Filmomhulde Tabletten			S	Other	250 Mg, Qd		Novartis	
	Plaquenil			S	Unknown	600 Mg, Qd		Not Reported	
	Plaquenil			S	Other	600 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2020	17930030	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000224			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	
	Prenatal Vitamins [Minerals Nos;Vitamins Nos]			C	Transplacental	Unk, Qd		Not Reported	
	Oxygen			C	Transplacental			Not Reported	
	Ceftriaxone			C	Transplacental			Not Reported	
	Metoprolol			C	Transplacental	25 Milligram, Q 12 Hr		Not Reported	
	Metoprolol			C	Transplacental	12.5 Milligram, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2020	17931844	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1789670		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Interaction; Long Qt Syndrome	Hidroxiclороquina Sulfato (2143su)	S	Oral	400 Mg	Teva
	Levofloxacinо (2791a)	S	Oral	500 Mg	Teva
	Kaletra 200 /50 Mg Comprимidos Recubiertos Con Pelicula, 120 Comprimid	S	Oral	2 Df	Not Reported
	Azitromicina (7019a)	S	Intravenous (not otherwise specified)	500 Mg	Not Reported
	Novorapid 100 U/MI Solucion Inyectable En Vial, 1 Vial De 10 MI	C	Subcutaneous	10 lu	Not Reported
	Oseltamivir (2885a)	C	Oral	75 Mg	Not Reported
	Piperacilina + Tazobactam	C	Intravenous (not otherwise specified)	1 Df	Not Reported
	Tocilizumab (8289a)	C	Intravenous (not otherwise specified)	600 Mg	Not Reported
	Losartan (7157a)	C	Oral	50 Mg	Not Reported
	Enoxaparina Sodica (2482so)	C	Subcutaneous	40 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17942756	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1791027		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hallucination	Hidroxiclороquina (2143a)			S	Oral			Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Interferon Beta-1b (2305od)			S		250 Mg		Not Reported
	Enoxaparina (2482a)			C				Not Reported
	Kaletra			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2020	17943135	NON-EXPEDITED			US-TEVA-2020-US-1791491			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Azithromycin Teva			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Blood Pressure
Decreased; Cough; Eating
Disorder; Eczema;
Pruritus; Scratch;
Somnolence

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17944670	EXPEDITED (15-DAY)		DE, OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-251095		67 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>
Cerebral Haemorrhage; Disease Progression; Fibrin D Dimer Increased; Pulmonary Haemorrhage; Thrombocytopenia	Azithromycine			S	Unknown	Unk		Sun
	Flucloxacillin			S	Unknown	Unk		Not Reported
	Ganciclovir			S	Unknown	Unk		Ranbaxy
	Levofloxacin			S	Unknown	Unk		Ranbaxy
	Linezolid			S	Unknown	Unk		Not Reported
	Sulphamethoxazole & Trimethoprim			S	Unknown	Unk		Mutual
	Voriconazole			S	Unknown	Unk		Not Reported
	Anidulafungin			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-Jun-2020	17948992	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1791447		68 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mixed Liver Injury	Azitromicina (7019a)			S	Oral	500 Milligram		Not Reported
	Micafungina Sodica (8263so)			S	Intravenous (not otherwise specified)			Not Reported
	Hidroxiclороquina Sulfato (2143su)			S	Oral	400 Milligram		Teva
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)			Not Reported
	Sulfametoxazol + Trimetoprima			S	Oral			Not Reported

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

Kaletra 200 /50 Mg Comprimidos
Recubiertos Con Pelicula, 120
Comprimid

S

Oral

2 Dosageform

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	17949650	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791451		46 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertransaminasaemia; Liver Function Test Abnormal	Azitromicina (7019a)			S	Unknown			Not Reported
	Hidroxiclороquina (2143a)			S	Unknown			Teva
	Ceftriaxona (501a)			S	Unknown			Not Reported
	Interf - Interferon (Sin Especificar)			S	Unknown			Not Reported
	Lopinavir+Ritonavir			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	17949836	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791449		81 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Hidroxiclороquina Sulfato (2143su)			S	Oral	400 Mg		Teva
	Kaletra 200 /50 Mg Comprimidos Recubiertos Con Pelicula, 120 Comprimid			S	Oral	2 Df		Not Reported
	Ceftriaxona (501a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17949838	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1791445		48 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delusional Disorder, Persecutory Type; Drug	Tacrolimus (2694a)			S	Oral	8 Mg		Not Reported

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

Interaction; Mixed Liver Injury	Azitromicina (7019a)	S	Oral	500 Mg	Not Reported
	Hidroxiclороquina Sulfato (2143su)	S	Oral	400 Mg	Teva
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	800 Mg	Not Reported
	Prednisona (886a)	S	Oral	20 Mg	Not Reported
	Metoclopramida (1958a)	S	Intravenous (not otherwise specified)	10 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2020	17951398	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1791217		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased; Hyperbilirubinaemia	Hidroxiclороquina 200 Mg Comprimido			S	Oral	200 Mg		Teva
	Azitromicina (7019a)			S	Oral			Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido			S	Oral	1 Dosage Forms		Not Reported
	Alopurinol 100 Mg 100 Comprimidos			C	Oral	100 Mg		Not Reported
	Simvastatina 10 Mg 28 Comprimidos			C	Oral	10 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2020	17953512	EXPEDITED (15-DAY)		OT	NVSC2020PL175212		5 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>
Chills; Seizure; Unresponsive To Stimuli	Azitrolek 250			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2020	17846771	EXPEDITED (15-DAY)		DE, OT	ES-TEVA-2020-ES-1241465		86 YR	Male	ESP

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

Completed Suicide; Depressed Mood	Hidroxiclороquina (2143a) Azitromicina (7019a) Metilprednisolona (888a) Kaletra	S S S S							Teva 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>
29-Jun-2020	17956049	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1791841		86 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hypertransaminasaemia; Long Qt Syndrome	Azitromicina (7019a) Hidroxiclороquina (2143a) Kaletra Metilprednisolona (888a)			S S S C				Not Reported Teva Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17944082	EXPEDITED (15-DAY)		OT	ES-EMD SERONO-E2B_90078167		69 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>
Hyperbilirubinaemia	Interferon Beta-1a Hydroxychloroquine Sulfate Levofloxacin (2791a) Kaletra Azitromicina (7019a)			S S S S S	Subcutaneous Oral Oral Oral			Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17960510	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1792785		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma	Azithromycine Ceftriaxone Sodique Previscan 20 Mg, Comprime Secable Lovenox			S S S S	Oral Subcutaneous Oral Subcutaneous	250mg 1g 20mg 4000 lu		Not Reported Not Reported Not Reported Not Reported

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

Ramipril	C	Not Reported
Diffu K	C	Not Reported
Seresta 10 Mg, Comprime	C	Not Reported
Verapamil (Chlorhydrate De)	C	Not Reported
Abasaglar	C	Not Reported
Phloroglucinol (Trimethyl Ether Du)	C	Not Reported
Doliprane	C	Not Reported
Furosemide	C	Not Reported
Macrogol 4000	C	Not Reported
Theralene	C	Not Reported
Tanganil	C	Not Reported
Januvia 100 Mg, Comprime	C	Not Reported
Pellicule		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2020	17960538	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1792784		92 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Prothrombin Time Shortened	Azithromycine			S	Oral	Unit Dose: 250mg, 500mg / D D1 Then 250 Mg / D		Not Reported
	Augmentin			S	Oral	1 Dosage Form		Not Reported
	Previscan 20 Mg, Comprime			S	Oral	20mg		Not Reported
	Secable							
	Zolpidem			C				Not Reported
	Forlax			C				Not Reported
	Furosemide			C				Not Reported
	Terbinafine			C				Not Reported
	Hydroxyzine (Dichlorhydrate De)			C				Not Reported
	Tramadol (Chlorhydrate De)			C				Not Reported
	Paracetamol			C				Not Reported
	Diffu K			C				Not Reported
	Tardyferon			C				Not Reported
	Laroxyl			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2020	17968865	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1793222		84 YR	Female	ESP

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Long Qt Syndrome	Hidroxiclорокина (2143a)			S	Oral	400 Mg W / 12 Hours Followed By 200 Mg W / 12 Hours		Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; Every 24 Hours		Not Reported
	Lopinavir/Ritonavir Accord 200 Mg/ 50 Mg Comprimidos Recubiertos Con P Ceftriaxona (501a)			S	Oral	400 Mg C/ 12h. 2 Dosage Forms		Not Reported
				S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Omeprazol (2141a)			C				Not Reported
	Deprax 100 Mg Comprimidos Recubiertos Con Pelicula Efg			C				Not Reported
	Rhinom - Rhinomer Nasal Spray			C				Not Reported
	Manidon Retard 120 Mg Comprimidos De Liberacion Prolongada			C				Not Reported
	Sintrom			C				Not Reported
	Paracetamol (12a)			C				Not Reported
	Duphalac 10 G Solucion Oral En Sobre			C				Not Reported
	Bisoprolol 2,5 Mg Comprimido			C				Not Reported
	Seretide			C				Not Reported
	Escitalopram (2858a)			C				Not Reported
	Humalog			C				Not Reported
	Furosemida (1615a)			C				Not Reported
	Alprazolam 1 Mg Comprimido			C				Not Reported
	Sinemet Plus Retard 25 Mg/100 Mg Comprimidos De Liberacion Prolongada			C				Not Reported
	Atrovent			C				Not Reported
	Noctamid 1 Mg Comprimidos			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	17975316	EXPEDITED (15-DAY)		HO	FR-NOVOPROD-735994		69 YR	Female	FRA

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

Rash Pustular	Novorapid	S	Subcutaneous	Unk	Novo Nordisk
	Atorvastatine [Atorvastatin]	S	Oral	20 Mg, Qd	Not Reported
	Lantus	S	Subcutaneous	Unk	Not Reported
	Furosemide	S	Oral	120 Mg, Qd	Not Reported
	Furosemide	S	Oral	Dose Decreased	Not Reported
	Advagraf	S	Oral	1 Df, Qd	Not Reported
	Cortancyl	S	Oral	7.5 Mg, Qd	Not Reported
	Azithromycine	S	Oral	Unk	Not Reported
	Flecaine	S	Oral	100 Mg, Qd	Not Reported
	Aranesp	S	Subcutaneous	40 Mg, Qw	Not Reported
	Atenolol	S	Oral	50 Mg, Qd	Not Reported
	Cholecalciferol	S	Oral	Unk	Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	Unk	Not Reported
	Loxen L P	S	Oral	100 Mg, Qd	Not Reported
	Allopurinol	S	Oral	300 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2020	17763559	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1232931		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Flutter; Cardio-Respiratory Arrest	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Kaletra			S	Oral	4 Dosage Forms Daily; Unit Dose: 2 Df Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 C		Not Reported
	Kaletra			S				Not Reported
	Dolquine			S	Oral	400 Milligram Daily; Dolquine 200 Mg		Not Reported

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

Dolquine			S			Comprimidos Recubiertos, 30 Comprimidos			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Jul-2020	17977372	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1794058		69 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Rash Pustular	Allopurinol			S	Oral	300 Mg		Actavis		
	Atenolol			S	Oral	50 Mg		Not Reported		
	Atorvastatine			S	Oral	20 Mg		Teva		
	Azithromycine			S	Oral			Not Reported		
	Cholecalciferol			S	Oral			Not Reported		
	Furosemide			S	Oral	120 Mg		Not Reported		
	Lantus			S	Subcutaneous			Not Reported		
	Novorapid			S	Subcutaneous			Not Reported		
	Advagraf 1 Mg, Gelule A Liberation Prolongee			S	Oral	1 Dosage Form		Not Reported		
	Cortancyl 5 Mg, Comprime			S	Oral	7.5 Mg		Not Reported		
	Flecaine 100 Mg, Comprime			S	Oral	100 Mg		Not Reported		
	Secable									
	Aranesp			S	Subcutaneous	40 Mcg		Not Reported		
	Plaquenil			S	Oral			Not Reported		
	Loxen L P 50 Mg, Gelule A Liberation Prolongee			S	Oral	100 Mg		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Jul-2020	17980319	NON-EXPEDITED			NVSC2020US187600			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Dizziness	Azithromycin 250mg Tablets			S	Unknown			Novartis		

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2020	17983520	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-02250			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Azithromycin Tablets, 500 Mg			S	Unknown	500 Milligram, Unk		Lupin	
	Rifampin Capsules Usp, 150 Mg			S	Unknown	150 Milligram, Unk		Lupin	
	Atovaquone Oral Suspension			S	Oral	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2020	17990788	EXPEDITED (15-DAY)		HO	NVSC2020FR190632		92 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>	
Prothrombin Time Shortened	Azithromycine Sandoz 250 Mg			S	Oral	500mg/J J1 Puis 250 Mg/J		Novartis	
	Filmomhulde Tabletten			S	Oral	1 Df, Qd		Not Reported	
	Augmentin			S	Oral	20 Mg, Qd		Not Reported	
	Previscan (Fluindione)			C	Unknown			Not Reported	
	Zolpidem			C	Unknown			Not Reported	
	Forlax			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
	Terbinafine			C	Unknown			Not Reported	
	Tramadol			C	Unknown			Not Reported	
	Paracetamol			C	Unknown			Not Reported	
	Diffu K			C	Unknown			Not Reported	
	Tardyferon			C	Unknown			Not Reported	
	Laroxyl			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	17996100	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1797383		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Retinal Detachment	Azitromicina (7019a)	S	Unknown	500 Mg	Not Reported
	Metilprednisolona (888a)	S	Unknown	Day 1: Bolus Of 80mg, From 08/04 To 16/04 In Descending Guide, Unit Dose: 40 Mg	Not Reported
	Lopinavir/Ritonavir 200 Mg/50 Mg Comprimido	S	Oral	2 Dosage Forms	Not Reported
	Ceftriaxona 2.000 Mg Inyectable Iv	S	Intravenous (not otherwise specified)	2 Gm, Form Of Admin. Text : Injection Iv	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos	S	Oral	200 Mg	Not Reported
	Metamizol 2.000 Mg Inyectable 5 MI	C			Not Reported
	Clexane 4.000 Ui (40 Mg)/ 0,4 MI Solucion Inyectable En Jeringa Preca	C			Not Reported
	Omeprazol 20 Mg Capsula	C			Not Reported
	Metoclopramida 10 Mg Inyectable 2 MI	C			Not Reported
	Paracetamol 1.000 Mg Inyectable Perfusion 100 MI	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	17999429	DIRECT	Y	OT			38 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>
Choking Sensation; Dyspnoea; Lip Swelling	Remdesivir			S	Intravenous (not otherwise specified)	Other Frequency:Once;		Gilead
	Azithromycin 500mg Daily			S				Not Reported
	Rocephin 1g Twice Daily			C				Not Reported
	Dexamethasone 6mg Iv Daily			C				Not Reported
	Zinc Sulfate			C				Not Reported
	Zyrtec 10mg Daily			C				Not Reported
	Duo Nebs			C				Not Reported
	Amlodipine 5mg Daily			C				Not Reported
	Ascorbic Acid 500mg Q12			C				Not Reported
	Colace			C				Not Reported
	Lovenox 40mg Daily			C				Not Reported
	Flonase Daily			C				Not Reported

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Singulair 10mg Daily			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18002069	NON-EXPEDITED			US-TEVA-2020-US-1799346		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation; Pain; Swelling	Azithromycin Teva			S	Unknown			Not Reported	
	Omeprazole Magnesium			S	Unknown	20 Milligram Daily; Omeprazole Magnesium Delayed Release Capsules Otc 20. 6 Mg - Drl 14 Ct		Not Reported	
	Famotidine Alembic			C	Unknown			Not Reported	
	Polyethylene Glycol Powder			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2020	18005207	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-033478		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Subdural Haematoma	Azithromycin Arrow Film-Coated Tablets 250mg			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Ceftriaxone			S	Intravenous drip	1 Gram, Once A Day		Not Reported	
	Previscan [Fluindione]			S	Oral	10 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18013878	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2020123846		37 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>	
Pancreatitis Acute	Amoxicillin			S	Oral	3 G, Qd		Glaxosmithkline	
	Levofloxacin			S	Oral	500 Mg, Qd		Glaxosmithkline	
	Seretide			S	Unknown	1000 ?G, Qd		Glaxosmithkline	
	Mupirocine			S	Unknown	Unk		Glaxosmithkline	

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	Paracetamol	S	Oral	3 G, Qd	Glaxosmithkline
	Seresta	S	Oral	20 Mg, Qd	Glaxosmithkline
	Esomeprazole	S	Oral	20 Mg, Qd	Glaxosmithkline
	Ebastine	S	Oral	20 Mg, Qd	Not Reported
	Fusidic Acid	S	Cutaneous	2 Df, Qd	Not Reported
	Clavulanic Acid	S	Oral	375 Mg, Qd	Not Reported
	Azithromycine	S	Oral	250 Mg, Qd	Not Reported
	Tamiflu	S	Oral	150 Mg, Qd	Not Reported
	Derinox (Naphazoline + Prednisolone)	S	Unknown	4 Df, Qd	Not Reported
	Symbicort Turbuhaler	S	Unknown	4 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2020	18014063	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-055622		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Duodenal Ulcer; International Normalised Ratio Increased; Labelled Drug-Drug Interaction Medication Error; Upper Gastrointestinal Haemorrhage	Coumadine			S	Oral	1 Dosageform, 1 Day		Bristol Myers Squibb
	Azithromycine			S	Oral	1000 Milligram, 1day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18016165	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA- 2020SE86421		37 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>
Pancreatitis Acute	Symbicort Turbuhaler			S	Respiratory (inhalation)	4 Dosage Form Daily		Astrazeneca
	Esomeprazole			S	Oral			Not Reported
	Ebastine			S	Oral			Not Reported

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

Acide Fusidique	S	Cutaneous	Not Reported
Acide Clavulanique	S	Oral	Not Reported
Amoxicilline	S	Oral	Not Reported
Azithromycine	S	Oral	Not Reported
Levofloxacin	S	Oral	Not Reported
Seretide	S	Respiratory (inhalation)	1000ug/Inhal Daily Not Reported
Tamiflu	S	Oral	Not Reported
Mupirocin	S	Nasal	Not Reported
Derinox (Naphazoline Nitrate)\Prednisolone\Phenylephrine)	S	Nasal	Not Reported
Paracetamol	S	Oral	Not Reported
Seresta	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2020	18022547	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1799316		71 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Depressed Level Of Consciousness; Dizziness; Nausea; Throat Irritation	Azitromicina (7019a)			S		1000 Milligram Daily; 1000 Mg / 1 Day And 500 Mg Rest		Not Reported
	Claritromicina (967a)			S		50 Mg		Not Reported
	Kaletra			S		800 Mg		Not Reported
	Dolquine			S		400 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18022655	EXPEDITED (15-DAY)		HO	FR-ROCHE-2639357		37 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>
Pancreatitis Acute	Tamiflu			S	Oral			Not Reported

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Ebastine	S	Oral	Not Reported
Acide Fusidique	S	Subcutaneous	Not Reported
Acide Clavulanique	S	Oral	Not Reported
Amoxicilline	S	Oral	Not Reported
Azithromycine	S	Oral	Not Reported
Levofloxacin	S	Oral	Not Reported
Seretide	S	Respiratory (inhalation)	Not Reported
Mupirocin	S	Nasal	Not Reported
Derinox (France)	S	Nasal	Not Reported
Paracetamol	S	Oral	Not Reported
Symbicort Turbuhaler	S	Respiratory (inhalation)	Not Reported
Seresta	S	Oral	Not Reported
Esomeprazole	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2020	18025438	EXPEDITED (15-DAY)		OT	AT-TEVA-2020-AT-1799842		61 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia Oral; Pruritus; Type I Hypersensitivity	Azithromycin Ratiopharm			S		P.O.		Not Reported	
	Tardyferon			C				Not Reported	
	Ulcusan			C				Not Reported	
	Proxen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Jul-2020	18025861	EXPEDITED (15-DAY)		DE, LT	ES-TEVA-2020-ES-1799298		82 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; Atrial Fibrillation; Blood Creatine Phosphokinase Mb	Azitromicina (7019a)			S		500 Mg / Day		Not Reported	
	Kaletra			S		532 Mg / 133.2 Mg / Day		Not Reported	

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Increased; Blood Creatinine Increased; Confusional State; Tachycardia	Levofloxacin (2791a)	S	Intravenous (not otherwise specified)	500 Mg / Day Iv	Not Reported
	Digoxina (770a)	S	Intravenous (not otherwise specified)	0.5 Mg/Iv	Not Reported
	Dolquine	S		800 Mg One Day, 400 Mg 4 Days	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	17896807	EXPEDITED (15-DAY)		OT	PHHY2019BR107231		59 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; Accidental Exposure To Product; Anosmia; Covid-19; Device Issue; Diarrhoea	Cosentyx			S	Unknown	300 Mg, Unknown		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Cosentyx			S	Unknown	Unk		Novartis
	Zimicina (Similar)			S	Unknown	Unk		Not Reported
	Predsim			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk Unk, Q4h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18028608	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1799874		61 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported
	Hidroxiclороquina Sulfato (2143su)			S	Oral	200 Mg		Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram		Not Reported
	Omeprazol (2141a)			C	Oral	20 Mg		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported
	Amlodipino (2503a)			C	Oral	5 Mg		Not Reported
	Paracetamol (12a)			C	Intravenous (not otherwise specified)	1 Gram		Not Reported

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Hidroxiclороquina Sulfato (2143su)			C	Oral	400 Mg	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034333	NON-EXPEDITED			US-TEVA-2020-US-1800830			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; Product Quality Issue; Product Taste Abnormal	Azithromycin Teva			S	Unknown	Start Date: From Last 7 Years		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2020	18034396	NON-EXPEDITED			US-TEVA-2020-US-1800956		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>	
Product Formulation Issue; Therapeutic Product Effect Variable	Azithromycin Teva			S	Unknown			Not Reported	
	Azithromycin Lupus			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18041085	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA201791		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>	
Clostridium Difficile Infection; Nosocomial Infection	Sandoz Azithromycin			S	Oral	500 Mg, Q24h		Novartis	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Q24h		Not Reported	
	Avelox			S	Unknown	400 Mg, Qd		Not Reported	
	Asa			C	Unknown	Unk		Not Reported	
	Dalteparin			C	Unknown	Unk		Not Reported	
	Divalproex Sodium			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Insulin Aspart			C	Unknown	Unk		Not Reported	
	Lansoprazole			C	Unknown	Unk		Not Reported	

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Levetiracetam	C	Unknown	Unk	Not Reported
Melatonin	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Metoprolol	C	Unknown	Unk	Not Reported
Oseltamivir	C	Unknown	Unk	Not Reported
Pantoloc	C	Unknown	Unk	Not Reported
Polyethylene Glycol 3350	C	Unknown	Unk	Not Reported
Potassium Citrate	C	Unknown	Unk	Not Reported
Quetiapine	C	Unknown	Unk	Not Reported
Rosuvastatin	C	Unknown	Unk	Not Reported
Sodium Phosphate	C	Unknown	Unk (Solution)	Not Reported
Ticagrelor	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk (Liquid)	Not Reported
Valproic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	17921302	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2020-029885		65 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>
Blood Lactate Dehydrogenase Increased; Covid-19 Treatment	Azithromycin Generis 500 Mg Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo
	Plaquinol			S	Oral	400 Milligram, Once A Day (400mg 12 / 12h On D1, 200mg 12 / 12h On The Following Days)		Not Reported
	Esomeprazole			C	Oral	Unk		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported
	Cyamemazine			C	Unknown	Unk		Not Reported
	Ramipril			C	Unknown	Unk		Not Reported

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Amlodipine	C	Unknown	Unk	Not Reported
Olanzapine	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2020	18042293	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1802242		37 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>
Pancreatitis Acute	Esomeprazole			S	Oral	20 Mg		Teva
	Ebastine			S	Oral	20 Mg		Not Reported
	Amoxicilline			S	Oral	3 Gram		Teva
	Paracetamol			S	Oral	3 Gram		Not Reported
	Levofloxacin			S	Oral	500 Mg		Teva
	Azithromycin			S	Oral	250 Mg		Not Reported
	Acide Fusidique			S	Cutaneous	2 Dosage Forms		Not Reported
	Acide Clavulanique			S	Oral	375 Mg		Not Reported
	Seretide			S	Respiratory (inhalation)	1000 Mcg		Not Reported
	Tamiflu			S	Oral	150 Mg		Not Reported
	Mupirocin			S	Nasal			Not Reported
	Derinox (Cetrimonium Bromide\Naphazoline Nitrate\Phenylephrine Hydrochloride\Prednisolone) Symbicort Turbuhaler			S	Nasal	4 Dosage Forms		Not Reported
				S	Respiratory (inhalation)	4 Dosage Forms		Not Reported
	Seresta 10 Mg, Comprime			S	Oral	20 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	17859022	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1243723		64 YR	Female	ESP

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

Hypofibrinogenaemia; Intentional Product Use Issue; Off Label Use	Hidroxiclороquina Sulfato (2143su	S	Oral	200 Mg	Teva
	Azitromicina (7019a)	S	Oral	500 Mg	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	1 Gm	Not Reported
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	400 Mg	Not Reported
	Enoxaparin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2020	18053664	EXPEDITED (15-DAY)		LT	ES-TEVA-2020-ES- 1803144		44 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Hidroxiclороquina (2143a)			S	Unknown	400 Mg		Teva
	Azitromicina (7019a)			S	Unknown	500 Mg / 24 The First Day And Then Low Dose At 250 Mg / 24		Not Reported
	Lopinavir (1271a)			S	Unknown	4 Dosage Forms Daily; 200/50 Every 2 Tablets Every 12 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2020	17920887	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2020-029886		72 YR	Male	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>
Covid-19 Treatment; Electrocardiogram Qt Prolonged	Azithromycin Generis 500 Mg Coated Tablets			S	Oral	Unk, 500mg D1 And 250mg In The Following Days		Aurobindo
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Amlodipine			C	Unknown	Unk		Not Reported
	Perindopril			C	Unknown	Unk		Not Reported
	Omeprazole			C	Unknown	Unk		Not Reported
	Calcium Polystyrene Sulfonate			C	Unknown	Unk		Not Reported

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

Plaquinol	C	Oral	Unk, 400 Mg, Twice A Day, Powder On D1 And 200 Mg, Twice A Day On The Following Days Pills	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-Jul-2020	18062591	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1803952		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Drug Interaction; Duodenal Ulcer; International Normalised Ratio Increased; Upper Gastrointestinal Haemorrhage	Azithromycine			S	Oral	1000 Mg		Not Reported
	Coumadine			S	Oral	1 Dosage Forms		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2020	18069728	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-029269		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Increased; Hypersensitivity; Palpitations	Azithromycin 250 Mg Tablets Usp			S	Unknown	250 Mg Tablets, 2 Tablets Initially And Then 1 Tablet Each Day After		Aurobindo
	Azithromycin 250 Mg Tablets Usp			S	Unknown	1 Dosage Form, Once A Day		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18089286	EXPEDITED (15-DAY)		DE	IT-BAUSCH-BL-2020-021577		72 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Metformin Hydrochloride			S	Oral			Santarus
	Zitromax			S	Oral			Not Reported
	Zyloric			S	Oral			Not Reported

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

	Cardura	C	Oral	Not Reported
	Lasix	C	Oral	Not Reported
	Ticlopidine Hydrochloride	C	Oral	Not Reported
	Actrapid	C	Subcutaneous	Not Reported
	Lobivon	C	Oral	Not Reported
	Entact	C	Oral	Not Reported
	Bivis	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18092585	EXPEDITED (15-DAY)		HO	US-SLATE RUN PHARMACEUTICALS- 20US000233			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Labour; Vaginal Discharge	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Albuterol Sulfate			C		Unk, Prn		Not Reported	
	Fexofenadine			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18092832	EXPEDITED (15-DAY)		OT	BR-SLATE RUN PHARMACEUTICALS- 20BR000236			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>	
Cardiovascular Insufficiency; Maternal Exposure During Pregnancy; Pulmonary Thrombosis	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Oxygen			C	Nasal	6 Litre Per Minute		Not Reported	
	Oxygen			C	Nasal	2 Litre Per Minute		Not Reported	
	Ceftriaxone			C	Unknown			Not Reported	
	Oseltamivir [Oseltamivir Phosphate]			C	Unknown			Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	

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

Noradrenaline (Norpinephrine)	C	Unknown	Not Reported
Midazolam	C	Unknown	Not Reported
Fentanyl	C	Unknown	Not Reported
Norepinephrine Bitartrate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18092998	EXPEDITED (15-DAY)		DE, OT	BR-SLATE RUN PHARMACEUTICALS- 20BR000237			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>	
Apgar Score Low; Foetal Distress Syndrome; Foetal Exposure During Pregnancy; Premature Baby	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18093285	EXPEDITED (15-DAY)		HO	BR-SLATE RUN PHARMACEUTICALS- 20BR000239			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>	
Foetal Exposure During Pregnancy; Maternal Exposure During Breast Feeding; Premature Baby	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	
	O2 [Oxygen]			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18093664	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000235			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; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Cerebral	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Hydroxychloroquine			C	Unknown	Unk		Not Reported	

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

Infarction; Foetal Death; Haemolysis; HELLP Syndrome; Maternal Exposure During Pregnancy; Off Label Use; Placental Disorder; Pre- Eclampsia; Thrombocytopenia	Hydroxychloroquine Ceftriaxone Ceftriaxone Tocilizumab	C C C C	Unknown Unknown Unknown Unk (Two Doses)	Unk Unk Unk Unk (Two Doses)	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>
30-Jul-2020	18093869	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000242			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Hainan Poly Pharmaceutical
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported
	Acetaminophen			C	Unknown			Not Reported
	Oxygen			C	Nasal	6 Litre		Not Reported
	Oxygen			C	Nasal	1 Litre		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18094073	EXPEDITED (15-DAY)		HO	US-SLATE RUN PHARMACEUTICALS- 20US000243			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>
Apgar Score Low; Foetal Exposure During Pregnancy; Premature Baby	Azithromycin Usp			S	Transplacental	500 Milligram, Qd		Hainan Poly Pharmaceutical
	Ceftriaxone			C	Transplacental	1 Gram, Qd		Not Reported
	Acetaminophen			C	Transplacental			Not Reported
	Oxygen			C	Transplacental	6 Litre		Not Reported
	Oxygen			C	Transplacental	1 Litre		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-Jul-2020	18094350	EXPEDITED (15-DAY)		OT	BR-SLATE RUN PHARMACEUTICALS- 20BR000238			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>	
Maternal Exposure During Pregnancy; Pulmonary Thrombosis	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Methyldopa			C	Unknown	1 Gram, Qd		Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Betamethasone			C		12 Milligram, Qd		Not Reported	
	Oxygen			C	Nasal	3 Litre Per Minute		Not Reported	
	Oxygen			C	Nasal	2 Litre Per Minute		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2020	18097399	EXPEDITED (15-DAY)		DE	NVSC2020IT212318		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Metformin Hydrochloride			S	Oral	850 Mg, Qd		Novartis	
	Zyloric			S	Oral	100 Mg, Qd		Not Reported	
	Zitromax			S	Oral	500 Mg, Qd		Not Reported	
	Cardura			C	Oral	2 Mg		Not Reported	
	Lasix			C	Oral	25 Mg		Not Reported	
	Lobivon			C	Oral	2.5 Mg		Not Reported	
	Ticlopidine Hydrochloride			C	Oral	500 Mg		Not Reported	
	Entact			C	Oral	20 Mg		Not Reported	
	Actrapid			C	Subcutaneous	70 Iu		Not Reported	
	Bivis			C	Oral	1 Df		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18097472	DIRECT		LT			59 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>
Blood Potassium Decreased; Blood Pressure Increased; Chest Discomfort; Drug Hypersensitivity; Feeling Hot; Heart Rate Increased; Hyperhidrosis; Rash	Azithromycin Tablet Usp, 250 Mg			S	Oral			Teva
	Baclofen			C				Not Reported
	Rosuvastatin			C				Not Reported
	Midodrine Hcl			C				Not Reported
	Levothyroxine			C				Not Reported
	Topiramate			C				Not Reported
	Zyrtec			C				Not Reported
	Multivitamin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2020	18099105	EXPEDITED (15-DAY)		DE	IT-EMD SERONO-9177651		72 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Metformin			S	Oral			Not Reported
	Zitromax			S	Oral			Not Reported
	Zyloric			S	Oral			Not Reported
	Ticlopidine Hydrochloride			C	Oral			Not Reported
	Actrapid /00646001/			C	Subcutaneous	40 Iu/MI		Not Reported
	Lobivon			C	Oral			Not Reported
	Entact			C	Oral			Not Reported
	Bivis			C	Oral	40 Mg/10 Mg		Not Reported
	Cardura			C	Oral			Not Reported
	Lasix /00032601/			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2020	18103055	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2020M1069037		72 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Metformin			S	Oral	850 Milligram, Qd		Not Reported
	Zyloric			S	Oral	100 Milligram, Qd		Mylan

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

Zitromax	S	Oral	500 Milligram, Qd	Mylan
Lasix /00032601/	C	Oral	25 Milligram	Mylan
Cardura	C	Oral	2 Milligram	Mylan
Ticlopidine Hydrochloride	C	Oral	500 Milligram	Mylan
Actrapid /00646001/	C	Subcutaneous	[Iu] (International Unit)	Mylan
Lobivon	C	Oral	2.5 Milligram	Mylan
Entact	C	Oral	20 Milligram	Mylan
Bivis	C	Oral	1 Dosage Form	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2020	18110193	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000245			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Oxygen			C	Nasal	Unk		Not Reported	
	Oxygen			C	Nasal	6 Litre / Minute		Not Reported	
	Vancomycin			C	Unknown			Not Reported	
	Piperacillin & Tazobactam			C	Unknown			Not Reported	
	Enoxaparin			C	Unknown	40 Milligram, Q 12 Hr		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2020	18110613	NON-EXPEDITED			US-SLATE RUN PHARMACEUTICALS- 20US000246			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Azithromycin Usp			S	Unknown	400 Milligram, Qd		Hainan Poly Pharmaceutical	
	Azithromycin Usp			S				Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	400 Milligram, Qd		Not Reported	
	Hydroxychloroquine			S				Not Reported	

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

Aspirine	C	Unknown	Not Reported
Aspirine	C		Not Reported
Statin [Atorvastatin Calcium]	C	Unknown	Not Reported
Statin [Atorvastatin Calcium]	C		Not Reported
Oxygen	C	Nasal	4 Litre Per Minute

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2020	18113134	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-255601		26 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy	Azithromycine			S	Unknown	Unk		Sun
	Hydroxychloroquine			S	Unknown	Unk		Ipca
	Infliximab			S	Unknown	Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone			S	Oral	Unk		Mutual
	Cyclosporine			S	Intravenous (not otherwise specified)	2 Milligram/Kilogram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	17835075	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC- 2020204780		73 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Covid-19; Electrocardiogram Qt Prolonged; Off Label Use; Potentiating Drug Interaction; Product Use In Unapproved Indication	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Once A Day		Pfizer
	Reuquinol			S		400 Mg, Every 12 Hours Before Sleep		Not Reported
	Reuquinol			S	Oral	400 Mg, Once A Day		Not Reported
	Oseltamivir			C		75 Mg, 2x/Day		Not Reported
	Oseltamivir			C		75 Mg, 1x/Day		Not Reported

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Tazocin	C	Intravenous (not otherwise specified)	4.5 G, 4x/Day Every 6 Hours	Not Reported
Tazocin	C	Intravenous (not otherwise specified)	4.5 G, 3x/Day Every 8 Hours	Not Reported
Sodium Bicarbonate	C	Intravenous (not otherwise specified)	Unk	Not Reported
Bromoprida	C	Intravenous (not otherwise specified)	10 Mg, 3x/Day Every 8 Hours	Not Reported
Potassium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	Unk	Not Reported
Cortisonal [Hydrocortisone]	C	Intravenous (not otherwise specified)	100 Mg, 2x/Day Every 12 Hours	Not Reported
Dormire [Midazolam Hydrochloride]	C	Intravenous (not otherwise specified)	100 Mg, As Needed	Not Reported
Encrise	C	Intravenous (not otherwise specified)	20 Iu, As Needed	Not Reported
Fentanest [Fentanyl Citrate]	C	Intravenous (not otherwise specified)	2500 Ug, As Needed	Not Reported
Norepinephrine Bitartrate	C	Intravenous (not otherwise specified)	32 Mg, As Needed	Not Reported
Hemofol	C	Subcutaneous	5000 Iu, 2x/Day (Every 12 Hours)	Not Reported
Hepamax S	C		Unk	Not Reported
Novalgina	C	Intravenous (not otherwise specified)	1 G, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2020	18105005	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2020-037229		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic	Metformin			S	Oral	850 Milligram, Once A Day		Aurobindo	

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Symptoms	Zyloric	S	Oral	100 Milligram, Once A Day	Not Reported
	Zitromax	S	Oral	500 Milligram, Once A Day	Not Reported
	Cardura	C	Oral	2 Milligram	Not Reported
	Lasix	C	Oral	25 Milligram	Not Reported
	Ticlopidine Hydrochloride	C	Oral	500 Milligram	Not Reported
	Actrapid	C	Subcutaneous	70 International Unit	Not Reported
	Lobivon	C	Oral	2.5 Milligram	Not Reported
	Entact	C	Oral	20 Milligram	Not Reported
	Bivis	C	Oral	1 Dosage Form	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2020	18123207	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1810167		72 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Metformin Hydrochloride			S	Oral	850mg		Actavis
	Zitromax 500 Mg Compresse			S	Oral	500mg		Not Reported
	Rivestite Con Film							
	Zyloric 100 Mg Compresse			S	Oral	100mg		Not Reported
	Cardura 2 Mg Compresse			C	Oral	2mg		Not Reported
	Lasix 25 Mg Compresse			C	Oral	25mg		Not Reported
	Ticlopidine Hydrochloride			C	Oral	500mg		Not Reported
	Actrapid 40 International Units/MI Solution For Injection			C	Subcutaneous	70 lu		Not Reported
	Lobivon 5 Mg Compresse			C	Oral	2.5mg		Not Reported
	Entact 20 Mg Compresse			C	Oral	20mg		Not Reported
	Rivestite Con Film							
	Bivis 40 Mg/10 Mg Compresse			C	Oral	1 Dosage Form		Not Reported
	Rivestite Con Film							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18131898	EXPEDITED (15-DAY)		HO, OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-218980		60 YR	Male	CHN

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>	
Nocardiosis; Treatment Failure	Prednisone			S	Oral	60 Milligram, Daily		Sun	
	Prednisone			S	Oral	35 Milligram, Daily		Sun	
	Cyclophosphamide			S	Intravenous (not otherwise specified)	0.6 Gram, Monthly		Not Reported	
	Cyclophosphamide			S				Not Reported	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Azithromycine			S	Unknown	Unk		Sun	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Caspofungin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2020	18138957	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-070638			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>	
Injection Site Pain	Azithromycin For Injection Usp 500mg			S	Intravenous (not otherwise specified)	Unk, Once Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-Aug-2020	18138960	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-069350			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>	
Burning Sensation	Azithromycin For Injection Usp 500mg			S	Intravenous (not otherwise specified)	500 Milligram, Two Times A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18142489	EXPEDITED (15-DAY)		DE	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-256720		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With	Metformin			S	Oral	850 Milligram, Daily		Sun	

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Eosinophilia And Systemic Symptoms	Zyloric 100 Mg Comprese	S	Oral	100 Milligram, Daily	Not Reported
	Zitromax 500 Mg Comprese	S	Oral	500 Milligram, Daily	Not Reported
	Rivestite Con Film				
	Cardura 2 Mg Comprese	C	Oral	2 Milligram, Unk	Not Reported
	Lasix 25 Mg Comprese	C	Oral	25 Milligram, Unk	Not Reported
	Ticlopidine Hydrochloride	C	Oral	500 Milligram, Unk	Not Reported
	Actrapid 40 International Units/ML Solution For Injection	C	Subcutaneous	70 International Unit, Unk	Not Reported
	Lobivon 5 Mg Comprese	C	Oral	2.5 Milligram, Unk	Not Reported
	Entact 20 Mg Comprese	C	Oral	20 Milligram, Unk	Not Reported
	Rivestite Con Film				
	Bivis 40 Mg/10 Mg Comprese	C	Oral	1 Dosage Form, Unk	Not Reported
	Rivestite Con Film				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18144531	EXPEDITED (15-DAY)		OT	NVSC2020DE221102			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>
Loss Of Consciousness; Overdose	Azithromycin 500 - 1 A Pharma			S	Unknown	3 Df, Once/Single		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2020	18124000	EXPEDITED (15-DAY)		DE, OT	IT-PFIZER INC-2020297138		72 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Reaction With Eosinophilia And Systemic Symptoms	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Metformin Hydrochloride			S	Oral	850 Mg, 1x/Day		Not Reported
	Zyloric			S	Oral	100 Mg, 1x/Day		Not Reported
	Cardura			C	Oral	2 Mg		Not Reported
	Lasix [Furosemide]			C	Oral	25 Mg		Not Reported
	Lobivon			C	Oral	2.5 Mg		Not Reported
	Ticlopidine Hydrochloride			C	Oral	500 Mg		Not Reported
	Entact			C	Oral	20 Mg		Not Reported

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	Actrapid	C	Subcutaneous	70 Iu				Not Reported	
	Bivis	C	Oral	1 Df				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2020	18164691	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000258			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Placenta Accreta; Placenta Praevia	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Ceftriaxone			C	Unknown			Not Reported	
	Oxygen			C	Nasal	40 Litre		Not Reported	
	Oxygen			C	Unknown	3 Litre/Min		Not Reported	
	Furosemide			C	Intravenous (not otherwise specified)	40 Milligram		Not Reported	
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2020	18164874	EXPEDITED (15-DAY)		CA, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000259			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>	
Apgar Score Low; Bradycardia Neonatal; Foetal Exposure During Pregnancy; Limb Malformation; Neonatal Respiratory Failure; Premature Baby	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	
	Ceftriaxone			C	Transplacental			Not Reported	
	Oxygen			C	Transplacental	40 Litre		Not Reported	
	Oxygen			C	Transplacental	3 Litre/Min		Not Reported	
	Furosemide			C	Transplacental	40 Milligram		Not Reported	
	Dexamethasone			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2020	18185992	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS		59 YR	Female	USA

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INC.-2020-03366

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Manufacturing Materials Issue	Azithromycin Tablets, 250 Mg			S	Unknown	250 Milligram		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2020	18188068	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000262			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qrs Complex Prolonged; Off Label Use; Tachycardia	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical
	Ibrutinib			C	Unknown	420 Milligram, Qd		Not Reported
	Ibrutinib			C	Unknown	140 Milligram, Qd		Not Reported
	Ibrutinib			C	Unknown	140 Milligram, Qd		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported
	Oxygen			C	Nasal	2 Litre		Not Reported
	Oxygen			C	Nasal	3 Litre		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2020	18189795	EXPEDITED (15-DAY)		OT	AU-SLATE RUN PHARMACEUTICALS- 20AU000261			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>
Atrioventricular Block First Degree; Drug Interaction; Off Label Use	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical
	Ivacaftor;Tezacaftor			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2020	18192903	EXPEDITED (15-DAY)		OT	NVSC2020SE231894			Female	SWE

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaundice; Ocular Icterus; Pruritus; Yellow Skin	Azithromycine			S	Unknown	500 Mg, Qd		Novartis	
	Hydroxychloroquine			S	Unknown	400 Mg, Qd		Not Reported	
	Zink			S	Unknown	120 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2020	18197848	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1819635		36 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Omeprazol (2141a)			S	Oral			Actavis	
	Ibuprofeno (1769a)			S	Oral			Actavis	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2020	18198036	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS-20US000265			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>	
Amniotic Cavity Infection; Maternal Exposure During Pregnancy; Off Label Use; Pre-Eclampsia; Premature Separation Of Placenta; Small Size Placenta; Suppressed Lactation	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Nitric Oxide			C				Not Reported	
	Remdesivir			C	Unknown			Not Reported	
	Plasma			C	Unknown			Not Reported	
	Tocilizumab			C	Unknown			Not Reported	
	Heparin			C	Intravenous (not otherwise specified)			Not Reported	
	Betamethasone			C	Unknown	1 Dosage Form		Not Reported	
	Magnesium Sulfate			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>
26-Aug-2020	18198519	EXPEDITED (15-DAY)		CA, HO, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000266			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>	
Apgar Score Low;	Azithromycin Usp			S	Transplacental			Hainan Poly	
Arrhythmia Neonatal;	Hydroxychloroquine			C	Transplacental			Pharmaceutical	
Atrial Septal Defect;	Nitric Oxide			C	Transplacental			Not Reported	
Coagulopathy; Foetal	Remdesivir			C	Transplacental			Not Reported	
Exposure During	Plasma			C	Transplacental			Not Reported	
Pregnancy;	Tocilizumab			C	Transplacental			Not Reported	
Intraventricular	Heparin			C	Transplacental			Not Reported	
Haemorrhage Neonatal;	Betamethasone			C	Transplacental	1 Dosage Form		Not Reported	
Meconium In Amniotic	Magnesium Sulfate			C	Transplacental			Not Reported	
Fluid; Neonatal									
Hypotension; Neonatal									
Respiratory Distress									
Syndromes; Neonatal									
Respiratory Failure;									
Newborn Persistent									
Pulmonary Hypertension;									
Patent Ductus Arteriosus;									
Premature Baby;									
Tuberous Sclerosis									
Complex; Umbilical Cord									
Around Neck									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2020	18199910	EXPEDITED (15-DAY)		OT	IT-ABBVIE-20K-083- 3484095-00		38 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase	Kaletra 200/50			S	Oral			Not Reported	
Increased; Hepatotoxicity;	Plaquenil			S	Oral			Not Reported	
Off Label Use	Zitromax			S	Oral	500 Mg Comprese Rivestite Con Film		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-Aug-2020	18206020	NON-EXPEDITED			US-TEVA-2020-US-1819442		57 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>	
Diarrhoea	Azithromycin Teva			S	Unknown			Not Reported	
	Xeljanz Xr			C	Unknown			Not Reported	
	Xeljanz Xr			C				Not Reported	
	Oxycodone			C	Unknown	10/325 Half A Pill Every 6 Hours		Not Reported	
	Trazodone			C	Unknown			Not Reported	
	Omperazol			C	Unknown			Not Reported	
	Celebrex			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2020	16573940	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1066170			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>	
Anxiety; Depression; Dizziness; Dyspnoea; Fatigue; Fear Of Disease; Hyperhidrosis; Hypertension; Impaired Quality Of Life; Mental Impairment; Nausea; Panic Attack; Sense Of Oppression	Valsartan Dura			S		160 Milligram, Qd		Mylan	
	Valsartan Dura			S		240 Milligram, Qd (1 In Morning And 1/2 In Evening)		Mylan	
	Valsartan Dura			S		240 Milligram, Pm (Not Reported The Evening Total 240 Mg Daily)		Mylan	
	Valsartan Dura			S		80 Milligram, Bid ((In The Morning And Evening)		Mylan	
	Valsartan 1a Pharma			S		Unk		Mylan	
	Valsartan			S		Unk		Mylan	
	Valsacor			S		Unk		Mylan	
	Valsacor			S		Unk		Mylan	
	Valsacor			S		Unk		Mylan	

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Metoprolol Ratiopharm /00376902/	S	Unk	Mylan
Metoprolol Ratiopharm /00376902/	S	Unk	Mylan
Metoprolol Ratiopharm /00376902/	S	Unk	Mylan
Metoprolol Ratiopharm /00376902/	S	Unk	Mylan
Metoprolol Ratiopharm /00376902/	S	Unk	Mylan
Metoprolol Ratiopharm /00376902/	S	Unk	Mylan
Metoprolol Abz	S	Unk	Mylan
Ramipril	S	Unk	Mylan
Amlodipin Dexcel [Amlodipine Maleate]	S	Unk	Mylan
Amlodipin Dexcel [Amlodipine Maleate]	S	Unk	Mylan
Amlodipin Dexcel [Amlodipine Maleate]	S	Unk	Mylan
Simva	S	Unk	Mylan
Simva	S	Unk	Mylan
Simva	S	Unk	Mylan
L-Thyroxin-Henning	S	Unk	Mylan
L-Thyroxin Aristo	S	Unk	Mylan
L-Thyroxin Aristo	S	Unk	Mylan
L-Thyrox Hexal	S	Unk	Mylan
L-Thyrox Hexal	S	Unk	Mylan
L-Thyrox Hexal	S	Unk	Mylan
Spiriva	S	Unk	Mylan
Spiriva	S	Unk	Mylan
Spiriva	S	Unk	Mylan
Spiriva	S	Unk	Mylan
Spiriva	S	Unk	Mylan
Spiriva	S	Unk	Mylan

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Berodual N	S	Unk	Mylan
Tavor /00273201/	S	Unk	Mylan
Cefuroxim Heumann	S	Unk	Mylan
Cefurox Basics Sun	S	Unk	Mylan
Minocyclin Ratiopharm	S	Unk	Mylan
Skid [Minocycline Hydrochloride]	S	Unk	Mylan
Clarilind	S	Unk	Mylan
Azithromycin Hec	S	Unk	Mylan
Fosfomycin Eberth	S	Unk	Mylan
Prednisolon /00016201/	S	Unk	Mylan
Diclo 1a Pharma	S	Unk	Mylan
Diclofenac Ratiopharm /00372302/	S	Unk	Mylan
Jext	S	Unk	Mylan
Celestene N	S	Unk	Mylan
Pantoprazol Heumann	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>
01-Sep-2020	18189941	EXPEDITED (15-DAY)		DE	US-SLATE RUN PHARMACEUTICALS- 20US000263			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; Hypercoagulation; Rash	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical	
	Hydroxychloroquine			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Furosemide			S	Unknown			Not Reported	
	Piperacillin + Tazobactam			S	Unknown			Not Reported	
	Oxygen			C	Nasal	4 Litre Per Minute		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-Sep-2020	18217397	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000267			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Off Label Use	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Oxygen			C	Nasal	4 Litre/Min		Not Reported	
	Oxygen			C		15 Litre/Min		Not Reported	
	Oxygen			C	Nasal	8 Litre/Min		Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Ceftriaxone			C	Unknown	Unk		Not Reported	
	Tocilizumab			C	Intravenous (not otherwise specified)	400 Milligram, Single		Not Reported	
	Enoxaparin			C	Intravenous (not otherwise specified)			Not Reported	
	Betamethasone			C	Unknown	Unk, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2020	18217647	EXPEDITED (15-DAY)		HO	US-SLATE RUN PHARMACEUTICALS- 20US000268			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Oxygen Saturation Decreased; Premature Baby	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	
	Oxygen			C	Transplacental	15 Litre/Min		Not Reported	
	Oxygen			C	Transplacental	8 Litre/Min		Not Reported	
	Hydroxychloroquine			C	Transplacental			Not Reported	
	Ceftriaxone			C	Transplacental			Not Reported	
	Tocilizumab			C	Transplacental	400 Milligram, Single		Not Reported	
	Enoxaparin			C	Transplacental			Not Reported	
	Betamethasone			C	Transplacental	Unk, Single		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2020	17974136	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2020251212		53 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome; Off Label Use; Product Use In Unapproved Indication	Azithromycine			S	Oral	500 Mg		Pfizer
	Azithromycine			S	Oral	250 Mg, Daily		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg		Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	400 Mg		Not Reported
	Norepinephrine			C	Intravenous (not otherwise specified)	Unk (32mg/42ml)		Not Reported
	Cefotaxime Sodium			C		2000 Mg, 3x/Day		Not Reported
	Bipreterax [Indapamide;Perindopril Arginine]			C	Oral	Unk (1 At The Morning)		Not Reported
	Janumet			C		2 Df (1 Tablet At The Morning And 1 Tablet At The Evening)		Not Reported
	Suxamethonium Chloride			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Etomidate			C	Intravenous bolus	30 Mg		Not Reported
	Lovenox [Enoxaparin Sodium]			C	Subcutaneous	4000 Iu		Not Reported
	Propofol			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Rovamycine [Spiramycin Adepace]			C	Intravenous (not otherwise specified)	6 Miu (Administered Once)		Not Reported
	Amlodipine			C		10 Mg (1 Tablet At The Evening)		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported

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02-Sep-2020	18220518	EXPEDITED (15-DAY)		HO, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-260006		28 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>	
Agranulocytosis	Paracetamol		Y	S	Unknown	()		Ohm Lab	
	Cefotaxime Base			S	Unknown	()		Not Reported	
	Thiamazole			S	Unknown	40 Milligram, Daily		Not Reported	
	Azithromycine			S	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18231708	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR- 1821973		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Linezolid			S	Intravenous drip	Unspecified		Teva	
	Azithromycine			S	Oral	Unspecified		Not Reported	
	Tienam			S	Intravenous drip	Unspecified		Not Reported	
	Plaquenil			S	Oral	Unspecified		Not Reported	
	Tazocilline			S	Intravenous drip	Unspecified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18233679	DIRECT	Y	DE			78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Pneumonia Legionella; Respiratory Arrest; Unresponsive To Stimuli	Remdesivir (Eua) (Remdesivir (Eua))			S	Intravenous (not otherwise specified)			Not Reported	
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported	
	Remdesivir (Eua) (Remdesivir (Eua))			S				Not Reported	
	Azithromycin (Azithromycin)			S	Intravenous (not			Not Reported	

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500mg/Vil Inj)	otherwise specified)	
Azithromycin (Azithromycin 500mg/Vil Inj)	S	Not Reported

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07-Sep-2020	18237829	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1823360		28 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>
Agranulocytosis	Paracetamol			S	Unknown			Not Reported
	Azithromycine			S	Unknown			Not Reported
	Cefotaxime Base			S				Not Reported
	Thiamazole			S		40 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>
08-Sep-2020	18202975	EXPEDITED (15-DAY)		DE, OT	NVSC2020BG235368		19 YR	Male	BGR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Cardiac Arrest; Confusional State; Hallucination; Hypertension; Hypoxia; Hypoxia; Intentional Product Use Issue; Off Label Use; Tachypnoea	Dexamethasone			S	Unknown	Unk (4 Mg/1 MI - 2x2 Amp)		Novartis
	Metamizole			S	Unknown	Unk (X 2 Capsamp. 500mg/MI 2 MI)		Not Reported
	Fraxiparine			S	Unknown	0.6 MI (1 Vial Mg/MI As Prescribed)		Not Reported
	Vancocin			S	Unknown	1 G, Bid (2x1.0)		Not Reported
	Roactemra			S	Unknown	Unk (400 Mg/20 MI)		Not Reported
	Roactemra			S	Unknown	Unk (200 Mg/20ml)		Not Reported
	Albunorm			S	Unknown	10 % 1 Total		Not Reported
	Albunorm			S	Unknown	Unk		Not Reported
	Somazina			S	Unknown	Unk (1000 Mg 4 MI 2x1 Amp)		Not Reported
	Calcium Gluconate			S	Unknown	Unk (8.94 Mg/MI - 10 MI - 2x1 Amp)		Not Reported
	Sinequan			S	Unknown	Unk (X 2 Caps)		Not Reported

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Sterofundin	S	Unknown	Unk (500 L - Eco-Vial - X500 MI)	Not Reported
Degan	S	Unknown	Unk (10 Mg - 2 MI - As Prescribed)	Not Reported
Chlophazolin	S	Unknown	Unk (0.15 Mg/MI - As Prescribed)	Not Reported
Diflazon	S	Unknown	Unk (2 Mg/1 MI - 100 MI - X 2 Vial)	Not Reported
Sodium Chloride	S	Unknown	0.9 % (100 MI Eco-Bottle By Prescription)	Not Reported
Serum Glucose	S	Intravenous (not otherwise specified)	500 MI (By Prescription)	Not Reported
Esomeprazole Magnesium	S	Unknown	40 Mg, Bid (2x1 Vial)	Not Reported
Clexane	S	Unknown	Unk (60 Mg/0.60 MI - X1vial)	Not Reported
Nutriflex Omega Plus	S	Unknown	Unk (875 MI - 2 Pcs)	Not Reported
Meropenem	S	Unknown	1 G, Tid (3x1.0)	Not Reported
Chloroquine	S	Unknown	250 Mg, Bid (2x1 Tablets)	Not Reported
Methylprednisolone	S	Unknown	Unk (40 Mg / 2 MI)	Not Reported
Bromhexine Hydrochloride	S	Unknown	Unk (4 Mg 2 MI - As Prescribed)	Not Reported
Carsil	S	Unknown	Unk (90 Mg * 30 Pcs. - According To The Scheme)	Not Reported
Quamatel	S	Unknown	20 Mg, Bid (2x1 Vial)	Not Reported
Flexidol Relax	S	Unknown	100 MI (5 Mg/MI)	Not Reported
Sumamed	S	Unknown	500 Mg (Vial)	Not Reported
Enterol [Attapulgate\Pectin\Phthalylsulfacetamide]	S	Unknown	Unk (250 Mg * 10 - 2x2 Caps)	Not Reported
Midazolam	S	Unknown	Unk (5 Mg - 5 5 MI - In Perfusion)	Not Reported
Paracetamol	S	Unknown	100 MI (10 Mg/MI)	Not Reported

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Meropen	S	Unknown	1000 Mg (3x1.0)	Not Reported
Azitrox	S	Unknown	Unk	Not Reported
Furosemide	S	Unknown	Unk (10 Mg/MI - As Prescribed)	Not Reported
Vitamiin C	S	Unknown	Unk (10 5 5 MI 2x4 Amp)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2020	18240535	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR- APL-2020-046451			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>
Anxiety; Depression; Dizziness; Dyspnoea; Fatigue; Fear Of Disease; Hyperhidrosis; Hypertension; Impaired Quality Of Life; Mental Impairment; Nausea; Panic Attack; Sense Of Oppression	Ramipril 5mg			S	Unknown	Unk		Aurobindo
	Valsartan 160mg			S	Unknown	Unk		Aurobindo
	Amlodipin Dexcel [Amlodipine Maleate]			S	Unknown	Unk		Not Reported
	Amlodipin Dexcel [Amlodipine Maleate]			S	Unknown	Unk		Not Reported
	Amlodipin Dexcel [Amlodipine Maleate]			S	Unknown	Unk		Not Reported
	Azithromycin Hec			S	Unknown	Unk		Not Reported
	Berodual N			S	Unknown	Unk		Not Reported
	Cefurox Basics Sun			S	Unknown	Unk		Not Reported
	Clarilind			S	Unknown	Unk		Not Reported
	Celestene N			S	Unknown	Unk		Not Reported
	Cefuroxim Heumann			S	Unknown	Unk		Not Reported
	Diclo 1a Pharma			S	Unknown	Unk		Not Reported
	Diclofenac Ratiopharm			S	Unknown	Unk		Not Reported
	Fosfomycin Eberth			S	Unknown	Unk		Not Reported
	Jext			S	Unknown	Unk		Not Reported
	L-Thyroxin-Henning			S	Unknown	Unk		Not Reported
	L-Thyrox Hexal			S	Unknown	Unk		Not Reported
	L-Thyrox Hexal			S	Unknown	Unk		Not Reported

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L-Thyrox Hexal	S	Unknown	Unk	Not Reported
L-Thyroxin Aristo	S	Unknown	Unk	Not Reported
L-Thyroxin Aristo	S	Unknown	Unk	Not Reported
Metoprolol Abz	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Minocyclin Ratiopharm	S	Unknown	Unk	Not Reported
Pantoprazol Heumann	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Skid [Minocycline Hydrochloride]	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Tavor (Lorazepam)	S	Unknown	Unk	Not Reported
Valsartan 1a Pharma	S	Unknown	Unk	Not Reported
Valsartan Dura	S	Unknown	80 Milligram, Two Times A Day (In The Morning And Evening)	Not Reported
Valsartan Dura	S	Unknown	160 Milligram, Once A Day	Not Reported
Valsartan Dura	S	Unknown	240 Milligram, Once A Day	Not Reported

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Valsartan Dura	S	Unknown	(1 In Morning And 1/2 In Evening) 240 Milligram, Once A Day, Pm (Not Reported The Evening Total 240 Mg Daily)	Not Reported
Valsacor	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2020	18241599	EXPEDITED (15-DAY)		HO, OT	NVSC2020DE242677			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>
Anxiety; Depression; Dizziness; Dyspnoea; Fatigue; Fear Of Disease; Hyperhidrosis; Hypertension; Mental Impairment; Nausea; Panic Attack; Sense Of Oppression	Valsartan 1a Pharma			S	Unknown	Unk		Novartis
	Valsartan			S	Unknown	Unk		Novartis
	Ramipril			S	Unknown	Unk		Not Reported
	L-Thyrox Hexal			S	Unknown	Unk		Not Reported
	L-Thyrox Hexal			S	Unknown	Unk		Not Reported
	L-Thyrox Hexal			S	Unknown	Unk		Not Reported
	Diclo 1a Pharma			S	Unknown	Unk		Not Reported
	Valsartan Dura			S	Unknown	160 Mg, Qd		Not Reported
	Valsartan Dura			S	Unknown	240 Mg, Qd (1 In Morning And 1/2 In Evening)		Not Reported
	Valsartan Dura			S	Unknown	240 Milligram, Pm (Not Reported The Evening Total 240 Mg Daily)		Not Reported
	Valsartan Dura			S	Unknown	160 Mg, Qd (80 Milligram, Bid ((In The Morning And Evening))		Not Reported
	Skid [Minocycline Hydrochloride]			S	Unknown	Unk		Not Reported
	Simva			S	Unknown	Unk		Not Reported

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Simva	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Cefurox	S	Unknown	Unk	Not Reported
L-Thyroxin-Henning	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk (Strength: 80 Mg)	Not Reported
Valsacor	S	Unknown	Unk (Strength: 80 Mg)	Not Reported
Valsacor	S	Unknown	Unk (Strength: 160 Mg)	Not Reported
Clarilind	S	Unknown	Unk	Not Reported
Azithromycin Hec	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Prednisolon	S	Unknown	Unk	Not Reported
Tavor (Lorazepam)	S	Unknown	Unk	Not Reported
Diclofenac Ratiopharm	S	Unknown	Unk	Not Reported
Pantoprazol Heumann	S	Unknown	Unk	Not Reported
Minocyclin Ratiopharm	S	Unknown	Unk	Not Reported
Cefuroxim Heumann	S	Unknown	Unk	Not Reported
L-Thyroxin Aristo	S	Unknown	Unk	Not Reported
L-Thyroxin Aristo	S	Unknown	Unk	Not Reported
Metoprolol Abz	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported

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

Metoprolol Ratiopharm	S	Unknown	Unk	Not Reported
Fosfomycin Eberth	S	Unknown	Unk	Not Reported
Jext	S	Unknown	Unk	Not Reported
Celestene N	S	Unknown	Unk	Not Reported
Amlodipin Dexcel [Amlodipine Maleate]	S	Unknown	Unk	Not Reported
Amlodipin Dexcel [Amlodipine Maleate]	S	Unknown	Unk	Not Reported
Amlodipin Dexcel [Amlodipine Maleate]	S	Unknown	Unk	Not Reported
Berodual N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2020	18154264	EXPEDITED (15-DAY)	DE		BG-ROCHE-2656505		19 YR	Male	BGR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Intentional Product Use Issue; Off Label Use	Roactemra			S	Unknown	400 Mg/20 MI		Not Reported
	Roactemra			S	Unknown	200 Mg/20ml		Not Reported
	Midazolam			S	Unknown	5 Mg - 5 5 MI - In Perfusion		Not Reported
	Quamatel			S	Unknown	2x1 Vial		Not Reported
	Diflazon			S	Unknown	2 Mg/1 MI - 100 MI - X 2 Vial		Not Reported
	Sodium Chloride			S	Unknown	100 MI Eco-Bottle By Prescription		Not Reported
	Carsil			S	Unknown	90 Mg * 30 Pcs. - According To The Scheme		Not Reported
	Calcium Gluconate			S	Unknown	8.94 Mg/MI - 10 MI - 2x1 Amp		Not Reported
	Vancocin			S	Unknown	2x1.0		Not Reported
	Fraxiparine			S	Unknown	1 Vial Mg/MI As Prescribed		Not Reported
	Sinequan			S	Unknown	X 2 Caps		Not Reported

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

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2020	18195219	EXPEDITED (15-DAY)		DE	BG-BAUSCH-BL-2020-024113		19 YR	Male	BGR

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>
Death	Dexamethasone			S	Unknown	4 Mg/1 MI - 2x2 Amp		Bausch And Lomb
	Sodium Chloride			S	Unknown	100 MI Eco-Bottle By Prescription		Not Reported
	Serum Glucose			S	Intravenous (not otherwise specified)	By Prescription		Not Reported
	Meropen (Meropenem)			S	Unknown	Vial (3x1.0)		Not Reported
	Albunorm			S	Unknown	Vial		Not Reported
	Sterofundin			S	Unknown	500 L - Eco-Vial - X500 MI		Not Reported
	Enterol (Saccharomyces Boulardii)			S	Unknown	250 Mg 10 - 2x2 Caps		Not Reported
	Fraxiparine			S	Unknown	1 Vial Mg/MI As Prescribed		Not Reported
	Sinequan			S	Unknown	X 2 Caps		Not Reported
	Sumamed			S	Unknown	Vial		Not Reported
	Bromhexine			S	Unknown	4 Mg 2 MI - As Prescribed		Not Reported
	Metamizole			S	Unknown	X 2 Caps Amp. 500mg/MI 2 MI		Not Reported
	Quamatel			S	Unknown	2x1 Vial		Not Reported
	Roactemra			S	Unknown	400 Mg/20 MI		Not Reported
	Roactemra			S	Unknown	200 Mg/20ml		Not Reported
	Flexidol Relax			S	Unknown	5 Mg/MI		Not Reported
	Chlophazolin			S	Unknown	0.15 Mg/MI - As Prescribed		Not Reported
	Calcium Gluconate			S	Unknown	8.94 Mg/MI - 10 MI - 2x1 Amp		Not Reported
	Methylprednisolone			S	Unknown	40 Mg / 2 MI		Not Reported
	Furosemide			S	Unknown	10 Mg/MI - As Prescribed		Not Reported
	Azitrox			S	Unknown			Not Reported
	Clexane			S	Unknown	60 Mg/0.60 MI - X1vial		Not Reported
	Degan			S	Unknown	10 Mg - 2 MI - As Prescribed		Not Reported

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

Esomeprazole	S	Unknown	2x1 Vial	Not Reported
Carsil	S	Unknown	90 Mg 30 Pcs. - According To The Scheme	Not Reported
Vancocin	S	Unknown	Vial (2x1.0)	Not Reported
Paracetamol	S	Unknown	10 Mg/ML	Not Reported
Meropenem	S	Unknown	Vial (3x1.0)	Not Reported
Midazolam	S	Unknown	5 Mg - 5 5 ML - In Perfusion	Not Reported
Vitamin C (Ascorbic Acid)	S	Unknown	10 5 5 ML 2x4 Amp	Not Reported
Chloroquine Phosphate	S	Unknown	2x1 Tablets	Not Reported
Somazina (Citicoline)	S	Unknown	1000 Mg 4 ML 2x1 Amp	Not Reported
Diflazon	S	Unknown	Vial, 2 Mg/1 ML - 100 ML - X 2 Vial	Not Reported
Nutriflex Omega Plus	S	Unknown	875 ML - 2 Pcs	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2020	18161149	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1814314		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder	Hidroxicloroquina (2143a)			S	Oral	400 Mg C / 12h Dc And 200mg C / 12 Maint		Teva	
	Hidroxicloroquina (2143a)			S				Teva	
	Azitromicina (7019a)			S	Oral	500mg Shock Dose And 250 Mg C / 24h Maintenance		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Dexametasona (722a)			S	Intravenous (not otherwise specified)	6mg C/24		Not Reported	
	Dexametasona (722a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Remdesivir (10009a)			S	Intravenous drip	100 Mg C/24h		Not Reported	

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

Remdesivir (10009a)	S	Not Reported
Midazolam (2256a)	C	Not Reported
Fentanilo (1543a)	C	Not Reported
Enoxaparina (2482a)	C	Not Reported
Cisatracurio (2738a)	C	Not Reported
Paracetamol (12a)	C	Not Reported
Omeprazol (2141a)	C	Not Reported
Enalapril (2142a)	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2020	18193429	EXPEDITED (15-DAY)		DE, OT	BG-ASTRAZENECA-2020SF05712		19 YR	Male	BGR

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

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

Methylprednisolone	S	Unknown	Amp 40 Mg / 2 MI	Not Reported
Furosemide	S	Unknown	10 Mg/MI - As Prescribed	Not Reported
Azitrox	S	Unknown		Not Reported
Clexane	S	Unknown	60 Mg/0.60 MI - X1vial	Not Reported
Dexamethasone	S	Unknown	4 Mg/1 MI - 2x2 Amp	Not Reported
Degan	S	Unknown	10 Mg - 2 MI - As Prescribed	Not Reported
Carsil	S	Unknown	90 Mg X 30 Pcs. - According To The Scheme	Not Reported
Vancocin	S	Unknown	1 G, 2 Into 1.0	Not Reported
Paracetamol	S	Unknown	10mg/MI100.0ml Unknown	Not Reported
Sodium Chloride	S	Unknown	0.9 Percent, 100 MI Eco-Bottle By Prescription	Not Reported
Midazolam	S	Unknown	5 Mg - 5 5 MI - In Perfusion	Not Reported
Vitamin C	S	Unknown	10 5 5 MI 2x4 Amp	Not Reported
Chloroquine Phosphate	S	Unknown	250 Mg 2 Into 1 Tablets	Not Reported
Somazina	S	Unknown	1000 Mg 4 MI 2x1 Amp	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2020	18238582	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1823617		62 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertransaminaemia	Azitromicina (7019a)			S		Unit Dose 500mg		Not Reported
	Hidroxiclороquina (2143a)			S		200mg		Teva
	Enoxaparina (2482a)			C	Subcutaneous			Not Reported
	Omeprazol (2141a)			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2020	18247502	EXPEDITED (15-DAY)		DE	BG-PFIZER INC-2020343658		19 YR	Male	BGR

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Intentional Product Use Issue; Off Label Use	Methylprednisolone			S		40 Mg / 2 MI		Pfizer
	Sinequan			S		2 Caps		Pfizer
	Esomeprazole Sodium			S		40 Mg, 2x1 Vial		Pfizer
	Meropenem			S		1 G, 3x1.0		Pfizer
	Meropen			S		1000 Mg, 3x1.0		Unknown
	Quamatel			S		20 Mg, 2x1 Vial		Not Reported
	Bromhexine			S		4 Mg 2 MI - As Prescribed		Not Reported
	Albunorm			S		10 %		Not Reported
	Vitamin C [Ascorbic Acid]			S		10 5 5 MI 2x4 Amp		Not Reported
	Roactemra			S		200 Mg/20ml		Not Reported
	Roactemra			S		400 Mg/20 MI		Not Reported
	Carsil			S		90 Mg * 30 Pcs. - According To The Scheme		Not Reported
	Dexamethasone			S		4 Mg/1 MI - 2x2 Amp		Not Reported
	Somazina [Citicoline]			S		1000 Mg 4 MI 2x1 Amp		Not Reported
	Vancocin			S		1 G, 2x1.0		Not Reported
	Nutriflex Omega Plus			S		875 MI - 2 Pcs		Not Reported
	Paracetamol			S		100 MI, 10 Mg/MI		Not Reported
	Clexane			S	Unknown	60 Mg/0.60 MI - X1vial		Not Reported
	Sodium Chloride			S		0.9 %, 100 MI Eco-Bottle By Prescription		Not Reported
	Midazolam			S		5 Mg - 5 5 MI - In Perfusion		Not Reported
	Sterofundin			S		500 L - Eco-Vial - X500 MI		Not Reported
	Diflazon			S		2 Mg/1 MI - 100 MI - X 2 Vial		Not Reported
	Furosemide			S		10 Mg/MI - As Prescribed		Not Reported
	Flexidol Relax			S		100 MI, 5 Mg/MI		Not Reported
	Chloroquine Phosphate			S		250 Mg, 2x1 Tablets		Not Reported

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Serum Glucose	S	Intravenous (not otherwise specified)	500 MI, By Prescription	Not Reported
Azitrox	S		Unk	Not Reported
Sumamed	S		500 Mg	Not Reported
Fraxiparine	S		0.6 MI, 1 Vial Mg/MI As Prescribed	Not Reported
Chlophazolin	S		0.15 Mg/MI - As Prescribed	Not Reported
Metamizole	S		X 2 Caps Amp. 500mg/MI 2 MI	Not Reported
Calcium Gluconate	S		8.94 Mg/MI - 10 MI - 2x1 Amp	Not Reported
Enterol [Saccharomyces Boulardii]	S		200 Mg * 10 - 2x2 Caps	Not Reported
Degan	S		10 Mg - 2 MI - As Prescribed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18255659	EXPEDITED (15-DAY)		DE	EE-009507513-2009EST003425		69 YR	Male	EST
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Keytruda			S	Intravenous (not otherwise specified)			Merck	
	Tazocin (Azithromycin)			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18260492	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1825643		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertransaminaemia	Hidroxiclороquina (2143a)			S		Unit Dose 200mg		Teva	
	Azitromicina (7019a)			S		Unit Dose 500mg		Not Reported	
	Lopinavir+Ritonavir			S		4 Dosage Forms Daily; 2		Not Reported	

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Polaramine		C		Cp / 12 Hours Unit Dose 6mg		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18262318	EXPEDITED (15-DAY)	CA, OT		FR- GLAXOSMITHKLINE- FR2020181402			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Absence Of Cranial Vault; Foetal Exposure During Pregnancy; Neural Tube Defect	Malarone			S	Transplacental	1 Df		Glaxosmithkline	
	Fluconazole			S	Transplacental	Unk		Glaxosmithkline	
	Albendazole			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycine			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18263980	NON-EXPEDITED	OT		US-SLATE RUN PHARMACEUTICALS- 20US000271			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical	
	Oxygen			C	Nasal			Not Reported	
	Hydroxychloroquine			C	Unknown			Not Reported	
	Ascorbic Acid			C	Unknown			Not Reported	
	Methylprednisolone			C	Unknown			Not Reported	
	Ceftriaxone			C	Unknown			Not Reported	
	Tocilizumab			C	Unknown			Not Reported	
	Remdesivir			C	Unknown			Not Reported	
	Enoxaparin			C	Unknown			Not Reported	
	Heparin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18264135	EXPEDITED (15-DAY)	HO, LT, OT		US-SLATE RUN PHARMACEUTICALS-			Unknown	USA

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20US000272

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apgar Score Low; Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Infantile Apnoea; Neonatal Respiratory Distress Syndrome; Poor Feeding Infant; Premature Baby; Sepsis Neonatal; Temperature Regulation Disorder	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical
	Oxygen			C	Transplacental			Not Reported
	Hydroxychloroquine			C	Transplacental			Not Reported
	Ascorbic Acid			C	Transplacental			Not Reported
	Methylprednisolone			C	Transplacental			Not Reported
	Ceftriaxone			C	Transplacental			Not Reported
	Tocilizumab			C	Transplacental			Not Reported
	Remdesivir			C	Transplacental			Not Reported
	Heparin			C	Transplacental			Not Reported
	Enoxaparin			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18264222	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000275			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Oxygen			C	Nasal			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Remdesivir			C	Unknown			Not Reported
	Heparin			C	Unknown			Not Reported
	Enoxaparin			C	Unknown			Not Reported

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Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2020	18264346	EXPEDITED (15-DAY)		HO, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000276			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Neonatal Respiratory Distress; Poor Feeding Infant; Premature Baby; Pulmonary Sequestration; Sepsis Neonatal; Transient Tachypnoea Of The Newborn	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical	
	Oxygen			C	Unknown	Unk		Not Reported	
	Oxygen			C	Transplacental			Not Reported	
	Hydroxychloroquine			C	Transplacental			Not Reported	
	Methylprednisolone			C	Transplacental			Not Reported	
	Ceftriaxone			C	Transplacental			Not Reported	
	Remdesivir			C	Transplacental			Not Reported	
	Heparin			C	Transplacental			Not Reported	
	Enoxaparin			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2020	18264811	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR- APL-2020-047282		57 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Azithromycin Film Coated Tablet 500 Mg			S	Unknown	500 Milligram, Once A Day (1 Dd 1 Tablet)		Aurobindo	
	Codeine			S	Unknown	1 Dosage Form, 3 Times A Day (2 Dd 1 Tablet En Om 22:00 2 Tabletten)		Not Reported	
	Remdesivir			S	Unknown	100 Milligram, Once A Day (1 Dd 100 Mg)		Not Reported	
	Clexane			C	Unknown	1 Dosage Form (Injectievloeistof, 10.000 le/MI (Eenheden Per Milliliter))		Not Reported	
	Oxazepam			C	Unknown	10 Milligram		Not Reported	

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

Pantoprazol	C	Unknown	40 Milligram	Not Reported
Dexamethason	C	Unknown	1 Dosage Form	Not Reported
Ceftriaxon	C	Unknown	2000 Milligram	Not Reported
Loperamide	C	Unknown	2 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>
15-Sep-2020	18268423	EXPEDITED (15-DAY)		HO, OT	DE-ALKEM LABORATORIES LIMITED-DE-ALKEM- 2019-11226			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>
Anxiety; Depression; Dizziness; Dyspnoea; Fatigue; Fear Of Disease; Hyperhidrosis; Hypertension; Impaired Quality Of Life; Mental Impairment; Nausea; Panic Attack; Sense Of Oppression	Cefuroxime Axetil			S	Unknown	Unk		Alkem
	Valsartan			S	Unknown	Unk		Alkem
	Cefuroxim Heumann			S	Unknown	Unk		Not Reported
	Diclo 1 A Pharma			S	Unknown	Unk		Not Reported
	Diclofenac Ratiopharm			S	Unknown	Unk		Not Reported
	Amlodipine Dexcel [Amlodipine Maleate]			S	Unknown	Unk		Not Reported
	Amlodipine Dexcel [Amlodipine Maleate]			S	Unknown	Unk		Not Reported
	Amlodipine Dexcel [Amlodipine Maleate]			S	Unknown	Unk		Not Reported
	Azithromycin Hec			S	Unknown	Unk		Not Reported
	Berodual N			S	Unknown	Unk		Not Reported
	Celestene (Betamethasone)			S	Unknown	Unk		Not Reported
	Clarilind			S	Unknown	Unk		Not Reported
	Fosfomycin Eberth			S	Unknown	Unk		Not Reported
	Jext			S	Unknown	Unk		Not Reported
	L-Thyroxin Aristo			S	Unknown	Unk		Not Reported
	L-Thyroxin Aristo			S	Unknown	Unk		Not Reported
	L-Thyroxin Henning			S	Unknown	Unk		Not Reported
	L-Thyrox Hexal			S	Unknown	Unk		Not Reported

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

L-Thyrox Hexal	S	Unknown	Unk	Not Reported
L-Thyrox Hexal	S	Unknown	Unk	Not Reported
Minocycline Ratiopharm	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Metoprolol Tartrate	S	Unknown	Unk	Not Reported
Metoprolol Abz	S	Unknown	Unk	Not Reported
Pantoprazol Heumann	S	Unknown	Unk	Not Reported
Prednisolone	S	Unknown	Unk	Not Reported
Ramipril	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	Unk	Not Reported
Skid	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Simva	S	Unknown	Unk	Not Reported
Tavor (Lorazepam)	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk	Not Reported
Valsartan 1a Pharma	S	Unknown	Unk	Not Reported
Valsartan Dura	S	Unknown	160 Milligram, Od, (Every	Not Reported

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

Valsartan Dura	S	Unknown	1 Day) 160 Milligram, Od, (Every 1 Day)	Not Reported
Valsartan Dura	S	Unknown	240 Milligram, Od, (Every 1 Day)	Not Reported
Valsartan Dura	S	Unknown	240 Milligram, Od, (Every 1 Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2020	18234660	EXPEDITED (15-DAY)		DE, OT	BG-MYLANLABS- 2020M1076287		19 YR	Male	BGR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Cardiac Arrest; Confusional State; Hallucination; Hypertension; Hypoxia; Intentional Product Use Issue; Off Label Use; Tachypnoea	Esomeprazole			S	Unknown	40 Milligram(2x1 Vial)		Mylan
	Diflazon			S	Unknown	Unk(2 Mg/1 MI - 100 MI - X 2 Vial)		Mylan
	Sodium Chloride			S	Unknown	0.9 Percent(100 MI Eco- Bottle By Prescription)		Mylan
	Vitamin C /00008001/			S	Unknown	Unk(10 5 5 MI 2x4 Amp)		Mylan
	Quamatel			S	Unknown	20 Milligram(2x1 Vial)		Mylan
	Sinequan			S	Unknown	Unk(X 2 Caps)		Mylan
	Bromhexine			S	Unknown	Unk(4 Mg 2 MI - As Prescribed)		Mylan
	Furosemide			S	Unknown	10 Milligram Per Millilitre(10 Mg/MI - As Prescribed)		Mylan
	Sumamed			S	Unknown	500 Milligram		Mylan
	Chlrophazolin			S	Unknown	0.15 Milligram Per Millilitre(0.15 Mg/MI - As Prescribed)		Mylan
	Nutriflex Omega Plus			S	Unknown	Unk(875 MI - 2 Pcs)		Mylan
	Fraxiparine			S	Unknown	0.6 Milliliter(1 Vial Mg/MI As Prescribed)		Mylan
	Meropen /01250501/			S	Unknown	1000 Milligram(3x1.0)		Mylan

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Meropen /01250501/	S	Unknown	1 Gram(3x1.0)	Mylan
Flexidol Relax	S	Unknown	100 Milliliter(5 Mg/MI)	Mylan
Calcium Gluconate	S	Unknown	8.94 Milligram Per Millilitre(8.94 Mg/MI - 10 MI - 2x1 Amp)	Mylan
Albunorm	S	Unknown	10 Percent, Total	Mylan
Dexamethasone	S	Unknown	Unk(4 Mg/1 MI - 2x2 Amp)	Mylan
Degan	S	Unknown	Unk(10 Mg - 2 MI - As Prescribed)	Mylan
Chloroquine Phosphate	S	Unknown	250 Milligram(2x1 Tablets-)	Mylan
Meropenem	S	Unknown	1 Gram(3x1.0)	Mylan
Enterol /00838001/	S	Unknown	Unk(250 Mg 10 - 2x2 Caps)	Mylan
Roactemra	S	Unknown	Unk(200 Mg/20ml)	Mylan
Roactemra	S	Unknown	Unk(400 Mg/20 MI)	Mylan
Vancocin	S	Unknown	1 Gram(2x1.0)	Mylan
Sterofundin	S	Unknown	Unk(500 L - Eco-Vial - X500 MI)	Mylan
Azitrox	S	Unknown	Unk	Mylan
Midazolam	S	Unknown	Unk(5 Mg - 5 5 MI - In Perfusion)	Mylan
Methylprednisolone	S	Unknown	Unk(40 Mg / 2 MI)	Mylan
Metamizole	S	Unknown	Unk(X 2 Caps)	Mylan
Metamizole	S	Unknown	Unk(X 2 Caps Amp. 500mg/MI 2 MI)	Mylan
Clexane	S	Unknown	Unk(60 Mg/0.60 MI - X1vial)	Mylan
Serum Glucose	S	Intravenous (not otherwise specified)	500 Milliliter(By Prescription)	Mylan
Paracetamol	S	Unknown	100 Milliliter(10 Mg/MI)	Mylan
Somazina /00434801/	S	Unknown	1000 Milligram(1000 Mg 4	Mylan

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Carsil S Unknown MI 2x1 Amp)
Unk990 Mg 30 Pcs. -
According To The
Scheme) Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2020	18265479	EXPEDITED (15-DAY)		HO, OT	DE-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-04			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>
Anxiety; Depression; Dizziness; Dyspnoea; Fatigue; Fear Of Disease; Hyperhidrosis; Hypertension; Impaired Quality Of Life; Mental Impairment; Nausea; Panic Attack; Sense Of Oppression	Valsartan 1a Pharma			S		Unk		Not Reported
	Diclo 1a Pharma			S		Unk		Not Reported
	Valsartan Dura			S		160 Milligram, Qd		Not Reported
	Valsartan Dura			S		240 Milligram, Qd (1 In Morning And 1/2 In Evening)		Not Reported
	Valsartan Dura			S		240 Milligram, Pm (Not Reported The Evening Total 240 Mg Daily)		Not Reported
	Valsartan Dura			S		80 Milligram, Bid ((In The Morning And Evening)		Not Reported
	Skid			S		Unk		Not Reported
	Simva			S		Unk		Not Reported
	Simva			S		Unk		Not Reported
	Cefurox Basics Sun			S		Unk		Not Reported
	L-Thyroxin-Henning			S		Unk		Not Reported
	Valsartan			S		Unk		Boehringer Ingelheim
	Valsartan			S				Boehringer Ingelheim
	Valsartan			S		Qd (1 In Morning And 1/2 In Evening)		Boehringer Ingelheim
	Valsartan			S		240 Milligram, Pm (Not Reported The Evening Total 240 Mg Daily)		Boehringer Ingelheim

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

Valsartan	S		80 Milligram, Bid ((In The Morning And Evening)	Boehringer Ingelheim
Valsartan	S			Boehringer Ingelheim
Valsartan	S			Boehringer Ingelheim
Valsartan	S			Boehringer Ingelheim
Valsacor	S		Unk	Not Reported
Valsacor	S		Unk	Not Reported
Valsacor	S			Not Reported
Clarilind	S		Unk	Not Reported
Azithromycin Hec	S		Unk	Not Reported
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Spiriva	S		Unk	Boehringer Ingelheim
Prednisolon [Prednisolone]	S		Unk	Not Reported
Tavor [Lorazepam]	S		Unk	Not Reported
Diclofenac Ratiopharm	S		Unk	Not Reported
[Diclofenac Sodium]				
Pantoprazol Heumann	S		Unk	Not Reported
Minocyclin Ratiopharm	S		Unk	Not Reported
Cefuroxim Heumann	S		Unk	Not Reported
L-Thyroxin Aristo	S		Unk	Not Reported
Metoprolol Abz	S	Unknown	Unk	Not Reported
Metoprolol Abz	S	Unknown		Not Reported
Metoprolol Abz	S	Unknown		Not Reported
Metoprolol Abz	S	Unknown		Not Reported
Metoprolol Abz	S	Unknown		Not Reported

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

Metoprolol Abz	S	Unknown		Not Reported
Fosfomycin Eberth	S		Unk	Not Reported
Jext	S		Unk	Not Reported
Celestene N	S		Unk	Not Reported
Amlodipin Dexcel [Amlodipine Maleate]	S		Unk	Not Reported
Amlodipin Dexcel [Amlodipine Maleate]	S		Unk	Not Reported
Amlodipin Dexcel [Amlodipine Maleate]	S		Unk	Not Reported
Berodual N	S		Unk	Not Reported
L-Thyroxine [Levothyroxine]	S		Unk	Not Reported
L-Thyroxine [Levothyroxine]	S		Unk	Not Reported
L-Thyroxine [Levothyroxine]	S		Unk	Not Reported
Ramipril	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18276376	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1826935		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Decreased Appetite; Nausea	Azithromicina (7019a)			S				Not Reported
	Hidroxicloroquina (2143a)			S				Teva
	Ceftriaxona (501a)			S				Not Reported
	Kaletra			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18277499	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS-20US000273			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Corticosteroids			C	Unknown			Not Reported
	Oxygen			C	Nasal			Not Reported

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

Hydroxychloroquine	C	Unknown	Not Reported
Ascorbic Acid	C	Unknown	Not Reported
Methylprednisolone	C	Unknown	Not Reported
Plasma	C	Unknown	Not Reported
Tocilizumab	C	Unknown	Not Reported
Remdesivir	C	Unknown	Not Reported
Heparin	C	Unknown	Not Reported
Enoxaparin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18277946	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000279			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Corticosteroids			C	Unknown			Not Reported
	Oxygen			C	Nasal			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Ascorbic Acid			C	Unknown			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Heparin			C	Unknown			Not Reported
	Enoxaparin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18278462	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000281			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown	Unk		Hainan Poly Pharmaceutical

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

Corticosteroids	C	Unknown	Antenatal	Not Reported
Oxygen	C	Nasal		Not Reported
Hydroxychloroquine	C	Unknown		Not Reported
Ascorbic Acid	C	Unknown		Not Reported
Ceftriaxone	C	Unknown		Not Reported
Tocilizumab	C	Unknown		Not Reported
Remdesivir	C	Unknown		Not Reported
Heparin	C	Unknown		Not Reported
Enoxaparin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18278630	EXPEDITED (15-DAY)		HO, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000274			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>
Apgar Score Low; Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Neonatal Respiratory Distress Syndrome; Poor Feeding Infant; Premature Baby; Temperature Regulation Disorder	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical
	Corticosteroids			C	Transplacental			Not Reported
	Oxygen			C	Transplacental			Not Reported
	Hydroxychloroquine			C	Transplacental			Not Reported
	Ascorbic Acid			C	Transplacental			Not Reported
	Methylprednisolone			C	Transplacental			Not Reported
	Plasma			C	Transplacental			Not Reported
	Tocilizumab			C	Transplacental			Not Reported
	Remdesivir			C	Transplacental			Not Reported
	Heparin			C	Transplacental			Not Reported
	Enoxaparin			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18278753	EXPEDITED (15-DAY)		HO, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000282			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apgar Score Low; Exposure Via Breast Milk; Foetal Exposure During Pregnancy; Infantile Apnoea; Neonatal Respiratory Distress; Poor Feeding Infant; Premature Baby; Temperature Regulation Disorder	Azithromycin Usp			S	Transmammary	Unk		Hainan Poly Pharmaceutical
	Azithromycin Usp			S	Transplacental	Unk		Hainan Poly Pharmaceutical
	Oxygen			C	Transmammary	Unk		Not Reported
	Oxygen			C	Transplacental	Unk		Not Reported
	Hydroxychloroquine			C	Transmammary	Unk		Not Reported
	Hydroxychloroquine			C	Transplacental			Not Reported
	Ascorbic Acid			C	Transmammary	Unk		Not Reported
	Ascorbic Acid			C	Transplacental			Not Reported
	Ceftriaxone			C	Transmammary	Unk		Not Reported
	Ceftriaxone			C	Transplacental			Not Reported
	Tocilizumab			C	Transmammary	Unk		Not Reported
	Tocilizumab			C	Transplacental			Not Reported
	Remdesivir			C	Transmammary	Unk		Not Reported
	Remdesivir			C	Transplacental			Not Reported
	Heparin			C	Transmammary	Unk		Not Reported
	Heparin			C	Transplacental			Not Reported
	Enoxaparin			C	Transmammary	Unk		Not Reported
	Enoxaparin			C	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18279079	EXPEDITED (15-DAY)		HO, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000280			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>
Anaemia Neonatal; Apgar Score Low; Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Infantile	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical
	Corticosteroids			C	Transplacental			Not Reported
	Oxygen			C	Transplacental			Not Reported

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

Apnoea; Necrotising Colitis; Neonatal Respiratory Distress Syndrome; Premature Baby; Temperature Regulation Disorder	Hydroxychloroquine Ascorbic Acid Ceftriaxone Tocilizumab Heparin Enoxaparin	C C C C C C	Transplacental Transplacental Transplacental Transplacental Transplacental Transplacental	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2020	18279252	NON-EXPEDITED		OT	US-SLATE RUN PHARMACEUTICALS- 20US000277			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical Not Reported
	Oxygen			C	Nasal			Not Reported
	Hydroxychloroquine			C	Unknown			Not Reported
	Ascorbic Acid			C	Unknown			Not Reported
	Methylprednisolone			C	Unknown			Not Reported
	Ceftriaxone			C	Unknown			Not Reported
	Tocilizumab			C	Unknown			Not Reported
	Remdesivir			C	Unknown			Not Reported
	Heparin			C	Unknown			Not Reported
	Enoxaparin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2020	18284919	EXPEDITED (15-DAY)		HO, LT, OT	US-SLATE RUN PHARMACEUTICALS- 20US000278			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Hyperbilirubinaemia Neonatal; Infantile	Azithromycin Usp			S	Transplacental			Hainan Poly Pharmaceutical Not Reported
	Oxygen			C	Unknown	Unk		Not Reported

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

Apnoea; Intraventricular Haemorrhage Neonatal; Neonatal Respiratory Distress; Poor Feeding Infant; Premature Baby; Temperature Regulation Disorder	Oxygen	C	Transplacental	Unk	Not Reported
	Hydroxychloroquine	C	Transplacental		Not Reported
	Ascorbic Acid	C	Transplacental		Not Reported
	Methylprednisolone	C	Transplacental		Not Reported
	Ceftriaxone	C	Transplacental		Not Reported
	Tocilizumab	C	Transplacental		Not Reported
	Remdesivir	C	Transplacental		Not Reported
	Heparin	C	Transplacental		Not Reported
	Enoxaparin	C	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2020	18299656	EXPEDITED (15-DAY)		OT	IR-LUPIN PHARMACEUTICALS INC.-2020-06276		11 YR	Female	IRN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use	Oseltamivir Phosphate Capsules			S	Unknown	45 Milligram, Bid		Lupin
	Ceftriaxone			S	Unknown	1 Gram, Bid (Capsule)		Lupin
	Azithromycin Tablets, 250 Mg			S	Unknown	250 Milligram, Qd		Lupin
	Azithromycin Tablets, 250 Mg			S	Unknown	Unk		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Unknown	200 Milligram, Bid		Lupin
	Hydroxychloroquine Sulfate Tablets			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2020	18305256	DIRECT	Y	RI			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea	Azithromycin (Azithromycin 500mg/Vil Inj)			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2020	16284840	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK081490			Female	CAN
<u>Preferred Term</u>	<u>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; Dyspnoea; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Malaise; Sleep Disorder Due To A General Medical Condition; Wheezing	Salbutamol Sulphate			S		100 ?G, Prn		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z; Monthly		Glaxosmithkline	
	Incruse Ellipta			S		62.5 ?G, Qd		Glaxosmithkline	
	Breo Ellipta			S		200 ?G, Qd		Glaxosmithkline	
	Azithromycine			S		250 Mg, Qd		Glaxosmithkline	
	Ventolin Nebules			S		1 Mg/MI		Glaxosmithkline	
	Ventolin Nebules			S		2.5 MI, Prn		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>
25-Sep-2020	18312109	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202009008805			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>	
Fibrin D Dimer Increased; Melaena; Off Label Use	Hydroxychloroquine			S	Oral	400 Mg, Bid		Concordia	
	Hydroxychloroquine			S	Oral	200 Mg, Bid		Concordia	
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Not Reported	
	Enoxaparin Sodium			S	Subcutaneous	1 Mg/Kg (80 Mg) Subcutaneous (Sq) Injection		Not Reported	
	Enoxaparin Sodium			S	Subcutaneous	40 Mg (0.5 Mg/Kg) Sq Q12h		Not Reported	
	Aspirin			S	Unknown	Unk		Not Reported	
	Azithromycin For Injection Usp 500mg			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported	
	Azithromycin 250mg Oral			S	Oral	250 Mg, Qd		Not Reported	
	Methylprednisolone			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>
27-Sep-2020	18316005	EXPEDITED (15-DAY)		CA	FR-TEVA-2020-FR-1831467			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Absence Of Cranial Vault; Neural Tube Defect	Azithromycine			S	Transplacental			Not Reported	
	Fluconazole			S	Transplacental			Not Reported	
	Malarone 250 Mg/100 Mg, Comprime Pellicule			S	Transplacental	1 Dosage Forms		Not Reported	
	Albendazole			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>
28-Sep-2020	16038950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2688707-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Ineffective; Macular Degeneration	Humira			S	Subcutaneous			Not Reported	
	Lomotil			S	Oral	0.025 + 2.5 Mg/ 1 Tablet Times A Day Or As Needed Every 6 Hours		Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	Clotrimaderm			S	Unknown			Not Reported	
	Apo Sulfatrim			S	Unknown			Not Reported	
	Invanz			S	Unknown			Not Reported	
	Apo Amoxi			S	Unknown			Not Reported	
	Statex [Morphine Sulfate]			S	Unknown			Not Reported	
	Apo Nadol			S	Unknown			Not Reported	
	Atorvastatine			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Pms Pregabalin			S	Unknown			Not Reported	
	Oracort [Triamcinolone Acetonide]			S	Unknown			Not Reported	
	M Cal (Colecalciferol\Calcium			S	Unknown			Not Reported	

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

Carbonate(Magnesium Sulfate)				
Jamp Azithromycin	S	Unknown		Not Reported
Act Clarithromycin	S	Unknown		Not Reported
Avamys	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Salinex [Sodium Chloride]	S	Nasal		Not Reported
Ms Ir	S	Unknown		Not Reported
Apo Hydro	S	Unknown		Not Reported
Pms-Desonide	S	Unknown		Not Reported
Pentasa	S	Unknown		Not Reported
Entocort	S	Unknown		Not Reported
Bisacodyl	S	Unknown		Not Reported
Peglyte	S	Unknown		Not Reported
Polysporin	S	Unknown		Not Reported
D-Tabs	S	Unknown		Not Reported
Eurocal	S	Unknown		Not Reported
Acetaminophene	S	Unknown		Not Reported
Kenalog	S	Intra-articular		Not Reported
Habitrol	S	Unknown		Not Reported
Thrive	S	Unknown		Not Reported
Taro-Mupirocin	S	Unknown		Not Reported
Metronidazole	S	Unknown		Not Reported
Ratio-Topisone	S	Unknown		Not Reported
Flovent	S	Unknown		Not Reported
Nicoderm	S	Unknown	Patch	Not Reported
Betaderm	S	Unknown		Not Reported
Alrex	S	Unknown		Not Reported
Refresh Tears	S	Ophthalmic		Not Reported
Glycerine	S	Unknown		Not Reported

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

Biacin XL	S	Unknown	Not Reported
Preservision Areds 2	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Sinus Rinse	S	Nasal	Not Reported
Cetirizine	S	Unknown	Not Reported
Bactroban	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Trimethoprim	S	Unknown	Not Reported
Morphine Sulfate	S	Unknown	Not Reported
Sodium Chloride	S	Nasal	Not Reported
Nicotine Polacrilex	S	Unknown	Not Reported
Mupirocin	S	Topical	Not Reported
Macrogol 3350	S	Unknown	Not Reported
Potassium Chloride	S	Unknown	Not Reported
Sodium Bicarbonate	S	Unknown	Not Reported
Chloride	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Atropine Sulfate	S	Oral	Not Reported
W/Diphenoxylate Hydrochloride			
Diphenoxylate Hydrochloride	S	Oral	Not Reported
Nicotine	S	Unknown	Not Reported
Gramicidin	S	Unknown	Not Reported
Neomycin Sulfate	S	Unknown	Not Reported
Polymyxin B Sulfate	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Amoxicillin	S	Unknown	Not Reported
Zinc Oxide	S	Unknown	Not Reported
Zeaxanthin	S	Unknown	Not Reported

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

Xantofyl Palmitate	S	Unknown	Not Reported
DI-Alpha Tocopheryl Acetate	S	Unknown	Not Reported
Cupric Oxide	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Vitamin D3	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Magnesium Sulfate	S	Unknown	Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Betamethasone Dipropionate	S	Unknown	Not Reported
Betamethasone	S	Unknown	Not Reported
Azithromycin Dihydrate	S	Unknown	Not Reported
Alprazolam	S	Unknown	Not Reported
Prednisone Teva	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
Betamethasone Valerate	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	S	Unknown	Not Reported
Amoxicillin Trihydrate	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported
Bactrim	S	Unknown	Not Reported
Pms Azithromycin	S	Unknown	Not Reported
Atorvastatin Calcium	S	Unknown	Not Reported
Budesonide	S	Unknown	Not Reported
Hydrochlorothiazide	S	Unknown	Not Reported
Mesalazine	S	Unknown	Not Reported
Ergocalciferol	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Unspecified Ingredient	S	Unknown	Not Reported

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

Riva Pantoprazole	S	Unknown	Not Reported
Teva Prednisone	S	Unknown	Not Reported
Unspecified Ingredient	S	Unknown	Not Reported
Unspecified Ingredient	S	Unknown	Not Reported
Pulmicort Nebuamp	S	Unknown	Not Reported
Calcium + Vitamin D	C		Not Reported
Valsartan	C		Not Reported
Inflectra	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2020	18319572	EXPEDITED (15-DAY)		OT	NL-TEVA-2020-NL-1830680		57 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Codeine Tablet 10mg / Brand Name Not Specified			S		1 Tablet Twice Daily And 2 Tablets At 22:00, 1 Dosage Form		Not Reported
	Azitromycine Tablet 500mg / Brand Name Not Specified			S		500 Milligram Daily;		Not Reported
	Remdesivir			S		100 Milligram Daily;		Not Reported
	Enoxaparine Injvlst 10.000ie/MI (100mg/MI) / Clexane Injvlst 2.000ie			C		10,000 Iu / MI, 1 Dosage Form, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Oxazepam Tablet 10mg / Brand Name Not Specified			C		10 Mg, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Pantoprazol Tablet Msr 40mg / Brand Name Not Specified			C		40 Mg , Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Dexamethason Injvlst 1mg/MI (Base) / Brand Name Not Specified			C		1 Dosage Form, Therapy Start Date And End Date: Asked But Unknown		Not Reported
	Ceftriaxon Infusiepoeder 2000mg / Brand Name Not			C		2000 Mg, Therapy Start Date And End Date: Asked		Not Reported

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

Specified		But Unknown	
Loperamide Capsule 2mg / Brand Name Not Specified	C	2 Mg, Therapy Start Date And End Date: Asked But Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<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-2020	18320605	EXPEDITED (15-DAY)		OT	TR-SLATE RUN PHARMACEUTICALS- 20TR000284			Unknown	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Antidiuretic Hormone Secretion	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical
	Hydroxychloroquine			S	Unknown			Not Reported
	Favipiravir			S	Unknown			Not Reported
	Low Molecular Weight Heparin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2020	18325611	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-00015		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Chest Discomfort; Myalgia	Azithromycin Tablets Usp, 500 Mg			S	Oral	500 Milligram, Qd		Lupin
	Simvastatin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2020	18326092	NON-EXPEDITED			IR-LUPIN PHARMACEUTICALS INC.-2020-00722		25 YR	Female	IRN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphthous Ulcer	Azithromycin Tablets, 500 Mg			S	Unknown	1 Gram, Qd (Two 500 Mg Tablets At The Same Time)		Lupin